UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

ERIC JACKSON, et. al.,

Plaintiffs,

v.

ALEJANDRO N. MAYORKAS, Secretary of Homeland Security, et al.,

Defendants.

Case No. 4:22-cv-0825-P

APPENDIX TO DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTIONS FOR CLASS CERTIFICATION AND A PRELIMINARY INJUNCTION

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Dated: October 7, 2022	Respectfully submitted,			
	BRIAN M. BOYNTON Principal Deputy Assistant Attorney General			
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	/s/ Johnny Walker CODY T. KNAPP (NY Bar #5715438) JOHNNY H. WALKER (D.C. Bar #991325) Trial Attorneys United States Department of Justice Civil Division, Federal Programs Branch 1100 L Street NW, Rm. 12304 Washington, D.C. 20530 Tel.: (202) 514-3183 / Fax: (202) 616-8460 Email: johnny.h.walker@usdoj.gov			

Counsel for Defendants

Exhibit 1

DECLARATION OF MAJOR SCOTT STANLEY

- I, Major Scott Stanley, hereby state and declare as follows:
- 1. I am an Army Preventive Medicine Officer. I hold a PhD in genetics and have over 10 years of experience working in novel drug and vaccine development prior to joining the Army. I am currently employed by the U.S. Army as the Joint Force Health Protection Officer. I have held this position since June of 2021. I previously served as the Medical Advisor to the Assistant Secretary of State for the Bureau of Population, Refugees, and Migration, Department of State. My responsibilities as the Joint Force Health Protection Officer include: coordinating with the Office of the Secretary of Defense, the Combatant Commands, and the Services on health service support and preventive medicine; providing expert analyses and medical recommendations impacting the Joint Force; providing Military medical advice to the Chairman of the Joint Chiefs of Staff through the Joint Staff Surgeon on all matters related to force health protection, including: Public Health, comprehensive health surveillance and risk management, laboratory services, and veterinary services; and providing expertise across the continuum of force health protection activities including medical intelligence, health threat analysis, infectious disease prevention, industrial hygiene, chemical, biological and toxic materials and medical countermeasures.
- 2. I am generally aware of the allegations set forth in the pleadings filed in this matter. This declaration is based on my personal knowledge, as well as information made available to me during the routine execution of my official duties.

COVID-19 IMPACTS ON THE FORCE

3. As of 5 August 2022, there have been 697,522 cases of Coronavirus Disease 2019 (COVID-19) in service members, civilian, contractors, and dependents across the Department of Defense (DoD). There have been 435,744 cases in service members alone, which have led to 96

service member deaths (89 were unvaccinated, 3 partially vaccinated, and 2 fully vaccinated but not boosted, and 2 with an unknown vaccination status (NGB)). There have been no deaths among active duty personnel since the vaccination deadlines, with over 98.9% of active duty personnel at least partially vaccinated (current as of 5 August 2022).

- 4. COVID-19 impacted all elements of DoD simultaneously, and required significant operational oversight by the Secretary of Defense, the Chairman of the Joint Chiefs of Staff, Secretaries of the Military Departments, the Under Secretaries of Defense, and all geographic and functional combatant commands (CCMD) (i.e., military commands that carry out broad missions and are composed of forces from the military departments) to execute their statutory responsibilities.
- 5. On March 25, 2020, then-Secretary of Defense Mark Esper enacted a 60-day stop movement order for all DoD uniformed and civilian personnel and their sponsored family members overseas. This measure was taken to aid in further prevention of the spread of COVID-19, to protect U.S. personnel and preserve the operational readiness of our global force.
- 6. Building upon previously enacted movement restrictions governing foreign travel, permanent change of station moves, temporary duty and personal leave, this stop movement order also impacted exercises, deployments, redeployments, and other global force management activities. Approximately 90,000 service members slated to deploy or redeploy within 60 days of its issuance were impacted by this stop movement order.
- 7. Specific examples of cancelled or curtailed training resulting from the dangers posed by the SARS-CoV-2 virus, which causes COVID-19, include the following. In March of 2020, 63 Fort Jackson recruits in a class of 940 had tested positive for the virus and caused a rescheduling of basic training activities. Also in March 2020, the United States Military Academy at West Point was on spring break when the seriousness of the pandemic came to light, forcing a

pause in the academic year until a plan could be developed to bring the cadets back to campus safely. In early April 2020, Secretary Esper authorized the Secretaries of the Military Departments to pause accessions training (i.e., training for new recruits) for two weeks. In May 2020, the Defender Europe 2020 exercise was originally supposed to deploy the largest force (20,000 service members) from the United States to Europe in over 20 years, but the event was modified to about 6,000 service members to limit troop movement. Reserve and National Guard units suspended monthly battle assemblies and drill as early as March and April 2020, and moved to virtual training. For instance, the Army Reserve announced on March 18, 2020, that it was suspending monthly battle assemblies. The Navy Reserve announced about the same time the suspension of drill weekends, and then on April 16 it announced that suspension would be extended. In Korea, United States Forces Korea (the command responsible for military operations in the country) was forced to limit travel outside of the country, and travel to and from Daegu was limited to mission-essential personnel only. In addition, the spread of the virus caused the DoD Education Activity (DoDEA) to cancel school for children in all of the schools in Daegu, and military commanders were forced to cancel all meetings, formations, and training events greater than 20 people, which severely impacted unit training which routinely requires service members to practice maneuvers and operations in large group settings.

8. Perhaps one of the more well-known examples of how the spread of COVID-19 could impact military operations, particularly among unvaccinated service members, is that of the U.S.S. Theodore Roosevelt, a nuclear-powered aircraft carrier with 4,779 personnel onboard. While conducting operations in the Pacific Ocean, the U.S.S. Theodore Roosevelt had to be diverted to the U.S. Naval Base Guam after an outbreak of SARS-CoV-2 occurred in an estimated

1,331 crew members, killing one, and resulting in the ship becoming non-operational. Since the U.S. Navy only has 11 aircraft carriers in the total inventory, this event represented a significant reduction in the Navy's operational capacity. This example highlights not only the operational impact unmitigated spread of SARS-CoV-2 could have on the military's ability to carry out operations, but also the increased risk of transmission to those who must carry out their duties in close-quarters environments, such as service members who must work in close contact with others, sleep in open bays with tightly packed bunks, or must work in the confined areas of a ship where it is believed that such close, confined working environments contributed to higher exposure to the virus and a higher risk of infection.

9. Over the first twenty months of the pandemic, approximately 19 major training events, many of which involved preparedness and readiness training with our foreign partners, had to be canceled as a result of COVID-19. These included major training events involving tens of thousands of personnel that focus on readiness and response to events spanning a wide range of national security and international objectives, including: responses to catastrophic natural disasters, multi-national exercises with international partners to defend against military aggression, training symposiums and exercises to enhance defenses to information infrastructures, and partner capacity training for security and stability operations. While travel restrictions have generally lessened in the U.S. and globally, they continue to impact DoD operations in U.S. counties with medium to high community levels for COVID-19 and abroad where some Host Nation restrictions remain as the state of the pandemic continues to evolve with the emergency of newer, more infectious variants.

¹ <u>The New England Journal of Medicine</u>, An Outbreak of Covid-19 on an Aircraft Carrier, https://www.nejm.org/doi/full/10.1056/NEJMoa2019375.

- 10. Further, unvaccinated individuals were unable to participate in some international training events because some partner nations had COVID-19 vaccination requirements or additional testing and quarantine requirements for country entry that degraded training value and involvement for unvaccinated individuals. There are still countries with vaccine requirements or quarantine requirements for unvaccinated individuals which would preclude an unvaccinated individual from participating in a military-to-military engagement with partner nations.
- 11. The loss of these training opportunities not only inhibited the development and sustainment of intra- and international relationship development that would otherwise allow for increased cooperation and understanding, but it prevented invaluable training opportunities that allow our forces, and our foreign partners, to practice interoperability and to strengthen their abilities to plan and execute combat, humanitarian, and security operations that are vital to the preservation of national security and the protection of our foreign interests.
- 12. As in the civilian health care system, in the early weeks and months of the pandemic, the DoD cancelled all non-essential medical procedures and surgeries and was further limited in its ability to provide medical appointments due to access restrictions to military treatment facilities (MTFs), the lack of available beds in the MTFs, and the burden on the military health system associated with caring for COVID-19 patients. This had the effect of reducing readiness as service members were, in some cases, unable to receive the care they needed to address non-emergency conditions and undergo routine medical and health assessments that are required under military directives to maintain medical readiness.
- 13. The military health system was also called on to support the COVID-19 response in the United States. In April of 2020, the Department of Defense converted the Jacob K. Javits Center in New York into an alternative care facility for more than 2,000 COVID-19 patients. The

United States Naval Ship (USNS) Comfort arrived in New York Harbor on March 30, 2020, while the USNS Mercy arrived in Los Angeles on March 27, 2020, to relieve pressure on local hospital systems so they could focus on life-saving COVID-19 related care. In December of 2021, the President announced plans to send an additional 1,000 military medical personnel to U.S. hospitals to join the roughly 240 personnel already deployed to seven states. These and other examples of DoD support to civil authorities served as a resource drain on the military health system and obviously directly exposed DoD personnel to the SARS-CoV-2virus.

- 14. Vaccinations for COVID-19 enabled the return to higher levels of occupancy in DoD facilities, and enabled DoD to hold in-person training, meetings, conferences, and other events. Vaccinations also permit service members to engage in joint training exercises with other countries that have vaccine requirements. It also reduced the testing burden on the DoD since in many instances individuals who are fully vaccinated were not required to submit to COVID-19 testing.
- 15. On May 26, 2020, the Secretary of Defense issued conditions-based guidance that enabled the resumption of some unrestricted official DoD travel based on the White House's Opening Up America Guidelines. On April 12, 2021, the Under Secretary of Defense for Personnel and Readiness published guidance removing some travel restrictions for fully vaccinated individuals and on September 24, 2021, the Deputy Secretary of Defense lifted travel restrictions for fully vaccinated DoD personnel.
- 16. According to the Director of the National Institute of Allergy and Infectious Diseases (NIAID), Dr. Anthony Fauci, as of January 2022, statistics for the U.S. population showed that an unvaccinated person has a 10-times greater chance of getting infected, a 17-times greater chance of getting hospitalized, and a 20-times chance of dying compared to a vaccinated

person.² Rates of COVID-19 cases between October and November of 2021 were lowest among fully vaccinated persons with a booster dose compared to those with just the primary series, and much lower than rates among unvaccinated persons (25.0, 87.7, and 347.8 per 100,000 population, respectively). In December of 2021, when Omicron was circulating widely, the same pattern holds (148.6, 254.8, and 725.6 per 100,000 population, for boosted, primary series only, and unvaccinated, respectively).

17. In November of 2021, the CDC found that unvaccinated individuals were 4-times more likely to test positive and 15-times more likely to die than a fully vaccinated individual. In December of 2021, unvaccinated individuals were 16 times more likely to be hospitalized with COVID-19. For hospitalized adults, the CDC found that unvaccinated people with a previous COVID-19 diagnosis were more than 5 times more likely to get re-infected than fully vaccinated people with no prior history of SARS-CoV-2 infection. This demonstrates that through the end of 2021, COVID-19 vaccines were effective at reducing the risk of becoming infected, more importantly, were highly effective at preventing hospitalizations and deaths. Although COVID-19 vaccine effectiveness (VE) has since decreased in terms of preventing infections with the emergence of the new variants and with the waning of vaccine-induced immunity, protection against hospitalization and death has remained high. The CDC published a study on January 19, 2022 that showed VE in terms of preventing hospitalization during the period when Omicron has been the dominant variant was 81% following the initial 2-shot series and 90% in those who were up to date with the recommended booster dose.

² 20 January 2022 Blue Star Families forum. Panel Speakers: Dr. Anthony Fauci, NIAID; LTG Ronald Place, Defense Health Agency; and Maj Gen Paul Friedrichs, Joint Staff Surgeon.

- 18. DoD specific data has been equally compelling in terms of demonstrating the value of vaccinations. Between July and November of 2021, non-fully-vaccinated active-duty service members had a 14.6-fold increased risk of being hospitalized when compared to fully vaccinated active-duty service members. In December 2021, unvaccinated adults were 16-times more likely to be hospitalized than vaccinated adults. Furthermore, unvaccinated adults over 50 years of age were 44 times more likely to be hospitalized than individuals who were vaccinated and received a booster dose. And as mentioned previously, of the 96 deaths among uniformed service members, 92 were not fully vaccinated (another two were of unknown vaccination status, and the remaining two had not received a booster dose). Perhaps most importantly, there have been no COVID-19 related deaths among active duty personnel since the vaccination deadlines have passed.
- 19. While some have pointed to the increase in the number of breakthrough cases in general, and with the Delta and Omicron variants in particular, as a reason to question the effectiveness of the vaccines, it is important to keep in mind that as vaccination rates increase among service members, vaccinated service members will make up a larger percentage of the In other words, vaccinated personnel are population available to become infected. disproportionately represented in the pool of individuals exposed to the virus that causes COVID-19. Taken to the extreme, if every service member were vaccinated, only vaccinated service members could have infections. It is important to view the number of breakthrough infections in proportion to the size of the population in question, not necessarily as a reflection of vaccine effectiveness. The same holds true for vaccine effectiveness against hospitalizations. An analysis of the number of active duty Service members hospitalized due to COVID-19 between 21 July 2020 and 21 July 2022 shows an incremental increase in protection against hospitalization going from the unvaccinated, to the partially vaccinated, to the fully vaccinated, to those who received a booster. Specifically, for Active Duty Service members hospitalized (direct care in the Military

Health System only) during this two-year window, 70% were not fully vaccinated (38% were unvaccinated, 32% were partially vaccinated). As above, it is important to keep in mind that the size of the unvaccinated population during this window was decidedly smaller than the fully vaccinated population, obscuring the tangible benefit against hospitalization for the fully vaccinated.

20. Other recent media reports have cited faster waning immunity from the primary series of COVID-19 vaccines than for natural infections as evidence that the vaccines are not necessary, and may even be harmful. In one specific example, a New England Journal of Medicine article³ reported effectiveness against symptomatic infections was highest in people who had received three doses of the Pfizer vaccine and been infected with COVID-19 (74%), previous infection alone was 50% effective, and receipt of initial two vaccine doses last year offered little, if any, protection against infection with the Omicron BA.2 sub-variant. While it is true that protection from infection wanes over time following either a COVID-19 infection or COVID-19 vaccination, protection resulting from vaccination occurs without the risks of a COVID-19 infection - a much safer way to acquire immunity. It is also important to note that the highest levels of protection reported in this study were in those cohorts that were up-to-date on their vaccines (meaning had received the recommended boosters), regardless of prior infection status. In terms of safety, 11 billion doses of COVID-19 vaccines have been administered globally, providing immense amounts of data validating the safety and efficacy of these vaccines; reputable analyses have consistently shown that the benefit-risk ratio remains overwhelmingly favorable for vaccinations to prevent significant illness or death.

³ Heba N. Altarawneh, et. al., 2022. Effects of Previous Infection and Vaccination on Symptomatic Omicron Infections. New England Journal of Medicine. Published on 15 June 2022 at NEJM.org.

- 21. The most recent CDC data shows that COVID-19 vaccines continue to be highly protective against severe illness and death, although they provide a lesser degree of protection against asymptomatic and mild infection in light of the latest variants⁴. The rates of COVID-19—associated hospitalization and death are substantially higher among unvaccinated adults than among those who are up to date with recommended COVID-19 vaccination, and emerging evidence suggests that vaccination before infection also provides some protection against post—COVID-19 conditions. Id.
- 22. Given the tangible protection the vaccines afford service members against serious illness, hospitalization, and death, it is clear that COVID-19 vaccines improve readiness and preserve the DoD's ability to accomplish its mission. If an individual tests positive for COVID-19, they are required to isolate and are unavailable to perform their duties, even if they are asymptomatic or have mild symptoms. They also put their fellow service members at risk of infection and hospitalization and further degrade the readiness of their units, their service, and the DoD. Additionally, the vaccines have provided huge benefits to preventing infections and transmission in the past, and going forward, the vaccines will continue to provide some protection against infection, and more significantly, reduce the incidence of serious illness, long-term complications, or death. Moreover, if an unvaccinated service member in a hostile area becomes seriously ill and requires a medical evaluation, it may risk the lives of other service members or may ultimately not be possible, thus endangering the member's life and affecting the unit's mission.

⁴ Massetti GM, Jackson BR, Brooks JT, et al. Summary of Guidance for Minimizing the Impact of COVID-19 on Individual Persons, Communities, and Health Care Systems — United States, August 2022. MMWR Morb Mortal Wkly Rep. ePub: 11 August 2022. DOI: http://dx.doi.org/10.15585/mmwr.mm7133e1

23. I am aware that this declaration may be filed in multiple cases for the purpose of defending the Secretary of Defense's directive to vaccinate Service members against the COVID-19.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 15, 2022 in Washington, DC.

STANLEY.SCOT Digitally signed by STANLEY.SCOTT.E.1169

T.E.116963765

Date: 2022.08.15
12:24:57 -04'00'

Scott Stanley, PhD
Major, United States Army
Joint Staff Force Health Protection Officer
Office of the Joint Staff Surgeon

Exhibit 2

DECLARATION OF COLONEL TONYA RANS

- I, Colonel Tonya Rans, hereby state and declare as follows:
- 1. I am currently employed by the U.S. Air Force as the Chief, Immunization Healthcare Division, Defense Health Agency Public Health Directorate, located in Falls Church, Virginia. I have held the position since June 2017. I am a medical doctor and have been board certified in Allergy/Immunology since 2008 and was a board certified Pediatrician from 2001-2015.
- 2. In my current role, my responsibilities include directing a responsive, evidence-based, patient-centered organization promoting optimal immunization healthcare for all DoD beneficiaries and those authorized to receive immunizations from DoD. This includes assisting in policy development, providing implementation guidance and education, and engaging in clinical studies through clinical collaboration. The Defense Health Agency-Immunization Healthcare Division (DHA-IHD) routinely engages with the medical representatives from the military departments, U.S. Coast Guard, Joint Staff, Combatant Commands, and others to develop standardized immunization implementation guidance in accordance with published policy for consistency across DoD where possible.
- 3. I am aware of the allegations set forth in the pleadings filed in this matter. This declaration is based on my personal knowledge, as well as information made available to me during the routine execution of my official duties.

Coronavirus Disease 2019 (COVID-19)

4. As part of my official duties, I served as a member of the COVID-19 Vaccine Distribution Operational Planning Team (OPT), which was directed to develop and implement DoD's COVID-19 Vaccine Distribution plan. The Coronavirus Task Force (CVTF) provided

overarching guidance to the OPT. The OPT provided routine and ad hoc updates on COVID-19 vaccine deliveries, administration, and adverse events to the CVTF.

- 5. The virus that causes COVID-19 disease is SARS-CoV-2, a ribonucleic acid (RNA) virus from the Coronavirus family. Like any RNA virus, the SARS-CoV-2 virus mutates and evolves constantly and regularly as it infects and replicates in host cells. Mutations that are beneficial to the virus (i.e., make the virus more easily spread between hosts, evade the immune system) are integrated into the viral genome, thereby increasing "survival" and replication opportunity. This has been seen with the SARS-CoV-2 Delta variant, which is twice as contagious as previous variants while the Omicron variant and subvariants are considered to be more transmissible than the Delta variant. However, not all mutations are beneficial to the virus some can result in virus death and therefore do not infect the host. This is part of the normal biology cycle of all viruses.
- 6. The latest reports from the U.S. Centers for Disease Control and Prevention (CDC) indicate that the SARS-CoV-2 virus spreads when an infected person breathes out droplets and very small particles that contain the virus.² These droplets and particles can be inhaled by other people or land on their eyes, noses, or mouth. In some circumstances, viral particles may contaminate surfaces and then may be transmitted to another person by touching the contaminated surface followed by touching the eye, nose, or mouth. People who are closer than 6 feet from the infected person are most likely to get infected, especially in areas where there is poor ventilation.

¹ https://www.yalemedicine.org/news/covid-19-variants-of-concern-omicron last accessed July 6, 2022.

² https://www.cdc.gov/coronavirus/2019-ncov/faq.html, last accessed July 6, 2022.

7. COVID-19 disease can cause acute symptoms such as fever/chills, cough, shortness of breath, fatigue, muscle aches, headache, nausea, vomiting, diarrhea, loss of sense of smell or taste and/or sore throat. Symptoms appear 2-14 days (usually within 4-5 days) after viral exposure.³ The infection can affect people in different ways: from asymptomatic, to limited and mild (for 2-3 days) to more severe (such as trouble breathing, chest pain, inability to think straight and inability to stay awake). Even with the availability of aggressive medical management and ventilator support in an intensive care setting for those with severe symptoms, over 6.3 million have died worldwide.⁴ As of June 22, 2022, CDC reports that over 86 million individuals in the U.S. have been diagnosed with COVID-19 disease, over 4.8 million have been hospitalized, and over 1 million have died (approximately 3 in 1,000 in the total U.S. population of 330 million).⁵ Per the CDC, the elderly and those with underlying medical history of cardiovascular disease, diabetes, chronic respiratory, liver, or kidney disease, smoking, being overweight or obese, HIV, certain intellectual or developmental disabilities, pregnancy, substance abuse disorders, a weakened immune system, transplant recipients, or cancer are more likely to develop serious illness. However, it is a misguided belief that those who are otherwise young and healthy could not develop severe, or even fatal, disease. During the acute infectious stage, the virus causes inflammatory cell death, resulting in the release of pro-inflammatory cytokines (proteins which

 $^{^3\} https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html, last accessed July 6, 2022.$

⁴ https://covid19.who.int/, last accessed July 6, 2022

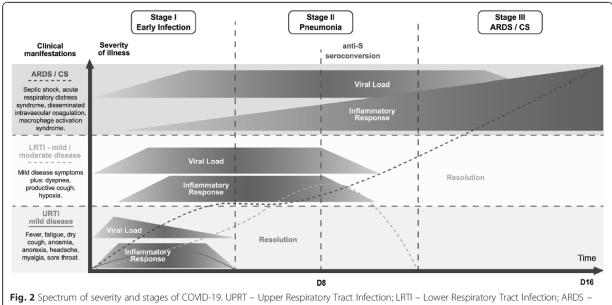
⁵ https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html, last accessed July 6, 2022.

⁶ https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html, last accessed July 6, 2022.

are important in cell signaling). Pro-inflammatory cytokines can cause inflammatory cell death within multiple organs. Cell death releases cellular and viral fragments, which results in production and release of more inflammatory cytokines. Disease progression can be curtailed by controlling the inflammatory process through immune system clearing of the virus. However, as depicted in the figure below, if the immune system is overwhelmed, either by viral immune evasive mechanisms or by an inadequate host response, the pro-inflammatory cytokine process may continue unabated, causing increasingly severe disease such as acute respiratory distress syndrome (ARDS) and cytokine storm. Recognition of the viral and hyperinflammatory phases informs treatment strategies for those with COVID-19 disease. Therapies that directly target the SARS-CoV-2 virus are anticipated to have the greatest effect early in the course of the disease, whereas immunosuppressive/anti-inflammatory/antithrombotic (anti-clotting) therapies are likely to be more beneficial after COVID-19 has progressed to stages characterized by low oxygen levels such as seen in ARDS.

⁷ Bordallo B, et al. Severe COVID-19: What Have We Learned With the Immunopathogenesis? *Adv Rheumatol* (2020) 60(1):50. doi: 10.1186/s42358-020-00151-7.

⁸ https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/, last accessed July 6, 2022.



Acute Respiratory Distress Syndrome; CS - Cytokine Storm

8. The strongest recommendation for pre-exposure to COVID-19 disease remains vaccination, with highest level of evidence demonstrated through robust randomized control trials. In contrast, the efficacy and/or outcomes of COVID-19 disease treatments are variable and depend on a person's underlying medical history, genetics, the COVID-19 variant causing disease, immune response, and interval between symptom onset and treatment initiation. Only one outpatient therapy, remdesivir, has received FDA approval to date. Other therapies are administered under a FDA emergency use authorization. ¹⁰ Just as it is acknowledged that there have been adverse events following COVID-19 vaccine receipt, it should also be understood that there are risks to COVID-19 disease treatment, even in those who are healthy enough to be managed in the outpatient setting. A non-exhaustive list of risks associated with COVID-19

⁹ https://www.covid19treatmentguidelines.nih.gov/overview/prevention-of-sars-cov-2/, last accessed July 6, 2022.

¹⁰ https://aspr.hhs.gov/COVID-19/Therapeutics/Documents/side-by-side-overview.pdf, last accessed July 6, 2022.

disease treatments includes cardiovascular and/or respiratory events, allergic reactions, fetal harm, and drug interactions. Further, some treatments must be administered shortly after diagnosis – within a matter of days – in order to be effective. ¹¹

9. Although most people with COVID-19 are better within weeks of illness, some experience post-COVID-19 conditions, most commonly referred to as long-COVID. Long-COVID-19 conditions are generally considered to include a wide range of new, returning, or ongoing health problems occurring four or more weeks after infection, lasting for at least 2 months and are not explained by an alternative diagnosis. Those who were asymptomatic during their COVID-19 infection may develop long-COVID-19. At present, there is no diagnostic test or cure for long-COVID; instead, treatment is geared towards symptom management. An April 2022 Government Accountability Office publication reported that an estimated 10 to 30% of US COVID-19 survivors develop long-COVID, (7.7 million to 23 million people) with potentially over 1 million workers being out of the labor force at any given time. 12 One systematic review assessing outcomes from 8,591 long COVID-19 survivors with symptoms over 12 months found that fatigue/weakness (28%), breathing difficulties (18%), joint and muscle discomfort (26%), depression (23%), anxiety (22%), memory loss (19%), concentration difficulties (18%), and insomnia (12%) were the most prevalent symptoms at one-year follow-up, with female patients and those with more severe initial illness were more likely to suffer from the sequelae after one year. 13 Another study comparing outcomes in patients referred to outpatient rehabilitation clinics

¹¹ *Id*.

¹² https://www.gao.gov/products/gao-22-105666, last accessed July 6, 2022

¹³ Han, Q, et al Long-Term Sequelae of COVID-19: A Systematic Review and Meta-Analysis of One-Year Follow-Up Studies on Post-COVID Symptoms. Pathogens 2022, 11, 269. https://doi.org/10.3390/pathogens11020269

after COVID-19 reported poorer general, mental, and physical health and functioning compared with patients with no previous diagnosis of COVID-19 referred for cancer rehabilitation. Those referred for rehabilitation following COVID-19 were more likely to be male, younger, and employed. 14 A recent Department of Veterans Affairs study described long-term cardiovascular outcomes of 153,760 people with COVID-19 who survived the first 30 days after infection as compared with controls.¹⁵ They provided evidence that, beyond the first 30 days of infection, people with a history of COVID-19 exhibited "increased risks and 12-month burdens of incident cardiovascular diseases, including cerebrovascular disorders (i.e. stroke), dysrhythmias (abnormal heart rhythms), inflammatory heart disease (i.e. myocarditis, pericarditis), ischemic heart disease (decreased blood flow to the heart), heart failure, thromboembolic disease (blood clots that can break loose and occlude a blood vessel), and other cardiac disorders." Of all cardiovascular diagnoses studied, the burdens of atrial fibrillation (AF) and heart failure (HF) were greatest. Risks of all cardiovascular disorders increased with severity of the acute COVID illness, with patients who required intensive care having particularly high risk. The authors report that the risks were evident regardless of age, race, sex, and other cardiovascular risk factors, including obesity, hypertension (high blood pressure), diabetes, chronic kidney disease, and hyperlipidemia (high cholesterol). Additionally, these risks were evident in people without any cardiovascular disease before COVID-19 exposure, "providing evidence that these cardiovascular risks might manifest even in people at low risk for cardiovascular disease." ¹⁶ A

¹⁴ Rogers-Brown JS, et al. CDC Morbidity and Mortality Weekly Report, Vol 70(27) 9 July 2021 https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7027a2-H.pdf.

¹⁵ Xie, Y., Xu, E., Bowe, B. *et al.* Long-term cardiovascular outcomes of COVID-19. *Nat Med* (2022). https://doi.org/10.1038/s41591-022-01689-3.

¹⁶ *Id*.

further study of multiple health care systems across the United States found that the incidence of cardiac complications after SARS-CoV-2 infection or mRNA COVID-19 vaccination were low overall but were significantly higher after infection than after vaccination for both males and females in all age groups.¹⁷

- Among males aged 12–17 years, the incidences of myocarditis and myocarditis or pericarditis were 50.1–64.9 cases per 100,000 after infection, 2.2–3.3 after the first vaccine dose, and 22.0–35.9 after the second dose; incidences of myocarditis, pericarditis, or multisystem inflammatory syndrome (MIS) were 150.5–180.0 after infection. Relative risk (RR) for cardiac outcomes comparing infected persons with first dose recipients were 4.9–69.0, and with second dose recipients, were 1.8–5.6; all RRs were statistically significant.
- Among males aged 18–29 years, the incidences of myocarditis and myocarditis or pericarditis were 55.3–100.6 cases per 100,000 after infection, 0.9–8.1 after the first vaccine dose, and 6.5–15.0 after the second dose; incidences of myocarditis, pericarditis, or MIS were 97.2–140.8 after infection. RRs for cardiac outcomes comparing infected persons with first dose recipients were 7.2–61.8, and with second dose recipients, were 6.7–8.5; all RRs were statistically significant.
- Among males aged ≥30 years, the incidences of myocarditis and myocarditis or
 pericarditis were 57.2–114.0 cases per 100,000 after infection, 0.9–7.3 after the first
 vaccine dose, and 0.5–7.3 after the second dose; incidences of myocarditis,

¹⁷ Block JP, et al. Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination – PCORnet, United States, January 2021-January 2022, Vol 71, No. 14 April 8, 2022 https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7114e1-H.pdf

pericarditis, or MIS were 109.1–136.8 after infection. RRs or cardiac outcomes among infected persons compared with first dose recipients were 10.7–67.2, and compared with second dose recipients, were 10.8-115.2; all RRs were statistically significant.

		Incidence* among males			Risk ratio (95% CI) SARS-CoV-2 infection versus mRNA COVID-19 vaccination				
Age group, yrs/	SARS CoV-2	mRNA COVID-19 vaccination cohort			mRNA COVID-19 vaccination cohort				
Outcome/ Risk window	infection cohort [†]	First dose [§]	Second dose ⁵	Unspecified dose ¹	Any dose**	First dose ⁹	Second dose [§]	Unspecified dose [¶]	Any dose**
5-11**									
Myocarditis									
7-day	12.6	0	0	0	0	NC	NC	NC	NC
21-day	17.6	4.0	0	6.5	3.2	4.4 (0.5-35.7)	NC	2.7 (0.3-22.1)	5.4 (1.1-26.1)
Myocarditis or									
7-day	12.6	0	0	0	0	NC	NC	NC	NC
21-day	17.6	4.0	0	6.5	3.2	4.4 (0.5-35.7)	NC	2.7 (0.3-22.1)	5.4 (1.1-26.1)
Myocarditis, pe		IIS55							
7-day	93.0	11	_	_	_	NC	NC	NC	NC
21-day	103.0	_	_	_	_	25.7 (3.5-187.0)	NC	16.0 (2.2-116.0)	31.7 (7.7–131.2)
42-day	133.2	_	_	_	_	33.3 (4.6-240.5)	28.2 (3.9-203.9)	10.3 (2.5-42.3)	20.5 (7.4-56.7)
12-17 ^{††}									
Myocarditis									
7-day	50.1	2.2	22.0	16.7	12.9	23.0 (5.3-99.5)	2.3 (1.2-4.4)	3.0 (1.3-6.7)	3.9 (2.1-7.0)
21-day	59.0	3.3	26.7	20.4	16.0	18.0 (5.4-60.6)	2.2 (1.2-4.0)	2.9 (1.4-6.0)	3.7 (2.1-6.4)
Myocarditis or	pericarditis								
7-day	56.0	2.2	26.7	22.3	16.0	25.7 (6.0-110.3)	2.1 (1.1-3.9)	2.5 (1.2-5.2)	3.5 (2.0-6.1)
21-day	64.9	3.3	35.9	29.7	21.6	19.8 (5.9-66.2)	1.8 (1.0-3.1)	2.2 (1.1-4.2)	3.0 (1.8-5.0)
Myocarditis, pe	ricarditis, or M	IIS ⁹⁹							
7-day	150.5	_	_	_	_	69.0 (16.8-283.2)	5.6 (3.5-9.2)	6.8 (3.6-12.7)	9.4 (6.2-14.4)
21-day	159.3	_	_	_	_	48.7 (15.2-155.7)	4.4 (2.9-6.9)	5.4 (3.1-9.4)	7.4 (5.0-10.8)
42-day	180.0	_	_	_	_	4.9 (3.2-7.4)	4.6 (3.0-6.9)	5.4 (3.2-9.1)	4.9 (3.5-6.7)
18-29									
Myocarditis									
7-day	55.3	0.9	6.5	7.0	4.6	61.8 (8.5-451.8)	8.5 (3.7-19.1)	7.9 (3.3-19.0)	12.0 (6.4-22.5)
21-day	63.7	3.6	8.4	11.6	7.5	17.8 (6.4-49.8)	7.6 (3.7-15.7)	5.5 (2.7-11.0)	8.4 (5.0-14.2)
Myocarditis or	pericarditis						_		
7-day	85.5	2.7	12.1	22.0	11.5	31.8 (9.9-102.0)	7.0 (3.8-12.9)	3.9 (2.3-6.6)	7.4 (4.8-11.5)
21-day	100.6	8.1	15.0	27.8	16.1	12.5 (6.2-25.2)	6.7 (3.9-11.7)	3.6 (2.3-5.8)	6.3 (4.3-9.1)
Myocarditis, pe	ricarditis, or M	IIS ⁹⁹							
7-day	97.2	_	_	_	_	36.2 (11.3-115.5)	8.0 (4.4-14.6)	4.4 (2.6-7.4)	8.5 (5.6-12.9)
21-day	112.3	_	_	_	_	13.9 (7.0-28.0)	7.5 (4.4-13.0)	4.0 (2.5-6.4)	7.0 (4.8-10.1)
42-day	140.8	_	_	_	_	7.2 (4.5-11.4)	8.4 (5.0-13.9)	4.5 (2.9-6.9)	6.4 (4.6-8.8)
≥30									
Myocarditis									
7-day	57.2	0.9	0.5	3.0	1.3	67.2 (31.4-143.8)	115.2 (42.6-311.7)	18.9 (11.2-31.7)	45.7 (30.2-69.2)
21-day	63.0	1.9	1.2	4.2	2.2	32.4 (19.3-54.3)	50.8 (26.7-96.4)	15.1 (9.7-23.7)	28.3 (20.4-39.3)
Avocarditis or	pericarditis								
7-day	100.2	3.8	3.1	15.0	6.3	26.6 (18.2-38.7)	32.3 (21.3-48.8)	6.7 (5.2-8.6)	16.0 (12.9-19.8)
1-day	114.0	7.3	7.3	20.1	10.4	15.6 (11.8-20.7)	15.6 (11.7-20.7)	5.7 (4.5-7.1)	10.9 (9.1–13.1)
Avocarditis, pe	ricarditis or M					,,	,		
'-day	109.1	_	_	_	_	28.9 (19.9-42.0)	35.1 (23.3-53.0)	7.3 (5.7-9.4)	17.4 (14.1-21.5)
21-day	123.0	_	_	_	_	16.8 (12.7–22.3)	16.8 (12.7–22.2)	6.1 (4.9–7.7)	11.8 (9.9–14.0)
42-day	136.8	_	_	_	_	10.7 (8.6-13.4)	10.8 (8.6-13.5)	5.4 (4.4-6.7)	8.7 (7.4-10.1)

An additional study of patients enrolled in Veterans Affairs system found an increased risk of diabetes among those who had tested positive for COVID-19 when compared to contemporary and historical control groups. The review of millions of records found that people who had been diagnosed with COVID-19 were 46% more likely to develop Type 2 diabetes for

reviations: MIS = multisystem inflammatory syndrome; NC = not canculated.

ses per 100,000 persons.

strons in the infection cohort included those who received ≥1 positive SARS-COV-2 molecular or antigen test result.

he first dose cohort included persons who had either the first of 2 doses ≥20 days before a second dose or a specific code for a first dose; the second cluded persons who had either the second of 2 doses ≥20 days after a first dose or a specific code for a second dose.

he unspecified dose cohort included persons who had a single dose that was not specified as first or second dose; doses specified as booster doses whe any dose cohort is the first, second, and unspecified dose cohorts combined; persons who had 2 doses are represented twice in the cohort but dex dates for their first and second doses.

NT162b2 (Pfizer-BioNTech) is the only mRNA COVID-19 vaccine approved for persons aged 5-17 years.

lagnoses of myocarditis, pericarditis, or MIS after a positive SARS-CoV-2 test result compared with diagnoses of myocarditis or pericarditis in this risk window was 4.0, 3 compared to the second doses.

NT162b2 (Pfizer-BioNTech) is the outcome and comparison. The incidence of myocarditis or pericarditis in this risk window was 4.0, 3 compared to the proper of the properties of th VID-19 vaccine approved for persons a r a positive SARS-CoV-2 test result com tcome and comparison. The incidence 7, 18–29, and ≥30 years after a first dos es per 100,000 for males aged 5-11, 12-17, 18-29, and ±30 years after a first decond dose; 12.9, 33.4, 31.3, and 25.2 cases per 100,000 after an unspecified di indicate the incidence for vaccination cohorts was not applicable because the myocarditis or pericarditis after vaccination.

the first time.¹⁸ In order to further investigate medical issues of and treatment for those afflicted with long-COVID, on April 5, 2022, President Biden issued a Presidential Memorandum "directing the Secretary of Health and Human Services (HHS) to coordinate a new effort across the federal government to develop and issue the first-ever interagency national research action plan on Long COVID. The effort will advance progress in prevention, diagnosis, treatment, and provision of services, supports, and interventions for individuals experiencing Long COVID and associated conditions. The Presidential Memorandum also directs HHS to issue a report outlining services and supports across federal agencies to assist people experiencing Long COVID, individuals who are dealing with a COVID-related loss, and people who are experiencing mental health and substance use issues related to the pandemic."¹⁹

COVID-19 Impacts on the Force

10. Infectious diseases have been the single greatest threat to the health of those involved in military operations. As the standard military unit shrinks and becomes more mobile to rapidly respond to global threats, any decrease in personal or unit readiness can significantly decrease operational efficiency and result in military ineffectiveness. Similar to other viruses, the SARS-CoV-2 virus can be easily transmitted to others prior to symptom development and therefore may infect significant numbers before being identified. DoD personnel, including service members, especially those in an operational setting (such as those working on ships, submarines, or engaged in the operation of aircraft and vehicles; those deployed to austere

¹⁸ Xie Y and Al-Aly Z. Risks and burdens of incident diabetes in long COVID: a cohort study *The Lancet, Diabetes and Endocrinology* Volume 10, Issue 5:311-321 https://www.thelancet.com/journals/landia/article/PIIS2213-8587(22)00044-4/fulltext.

¹⁹ https://www.whitehouse.gov/briefing-room/statements-releases/2022/04/05/fact-sheet-the-biden-administration-accelerates-whole-of-government-effort-to-prevent-detect-and-treat-long-covid/, last accessed July 7, 2022

environments; or those engaged in routine field training and airborne exercises) work in environments where duties may limit the ability to strictly comply with mitigation measures such as wearing a face mask, avoiding crowded areas, maintaining physical distancing of at least 6 feet, increasing indoor ventilation, maintaining good hand hygiene, and quarantining if in close contact with a COVID-19 case. 20 Therefore, upon exposure, these individuals may be at higher risk to be diagnosed with COVID-19 compared to those who can robustly maintain all recommended mitigation strategies. Further, although the elderly population and those with medical conditions are more likely to have severe disease, otherwise healthy Service members have developed long-COVID-19, potentially impacting their long-term ability to successfully perform their duties. Some service members have unfortunately succumbed to the disease, as described further below. Service members and federal civilian employees are the military's most valuable asset; without a medically ready force and ready medical force, the military mission is at high risk of failure. Recommendations from evidence-based medicine must remain the core approach to medical readiness. These evidence-based recommendations will continue to be updated as our understanding of the disease, complications, and impact from vaccination continues to evolve.

11. Between February 2020 and June 2022, there were 435,729 new and repeat cases of COVID-19 among active duty service members (**Table**). The largest monthly peak in cases occurred in January 2022, with 125,597 cases identified (Figure). The percentage of cases that were hospitalized was highest at the start of the pandemic and trended downward through

²⁰ The U.S. military's rapid response to the crisis in Ukraine and the surrounding areas serves as a prime example of the difficulty in not only predicting where and when service members will be required to serve, but also of the challenges in preventing the spread of COVID-19 and other diseases in undeveloped and austere environments. See, e.g.,

https://www.dvidshub.net/image/7065893/82nd-airborne-division-place-their-equipment-insidetent-they-settle-their-new-location, posted February 20, 2022.

January 2021. The percentage of hospitalized cases then increased from 0.9% in January 2021 to 1.9% in May and July 2021, and decreased to 0.4% in December 2021. The percentage of hospitalized cases remained low at 0.3% in January 2022 but increased to 0.9% in February 2022 and then dropped to 0.2% in June 2022. However, this recent trend should be interpreted with caution due to data lags. In total, 31 active duty service members have died from COVID-19 as of the end of June 2022. The number of active duty service members who died from COVID-19 remained very low throughout the first year of the pandemic, with a slight increase in the numbers of deaths occurring between December 2020 and February 2021, and a greater increase occurring between August and October 2021, coinciding with the increased spread of the Delta variant. More than one-half of the 31 deaths in active duty service members occurred between August and October 2021 (n=17). The most recently reported active duty service member death occurred in November 2021.

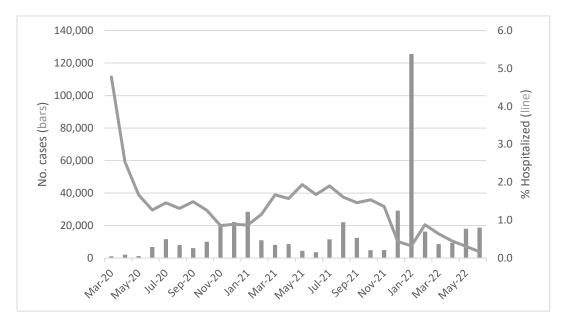
Table. COVID-19 cases, hospitalizations, and deaths among active duty service members, February 2020 - June 2022

	No.	No. %		
	cases	hospitalizations	hospitalizations	No. deaths
Feb-20	7	2	28.6	0
Mar-20	1,151	55	4.8	0
Apr-20	2,129	54	2.5	1
May-20	1,203	20	1.7	0
Jun-20	6,791	86	1.3	0
Jul-20	11,609	169	1.5	0
Aug-20	8,013	105	1.3	0
Sep-20	6,118	91	1.5	0
Oct-20	10,073	127	1.3	1
Nov-20	20,443	175	0.9	0

Dec-20	22,153	198	0.9	2
Jan-21	28,463	248	0.9	2
Feb-21	10,992	127	1.2	5
Mar-21	8,154	136	1.7	0
Apr-21	8,595	135	1.6	1
May-21	4,438	86	1.9	0
Jun-21	3,579	60	1.7	0
Jul-21	11,599	221	1.9	1
Aug-21	22,099	356	1.6	5
Sep-21	12,470	182	1.5	6
Oct-21	4,820	74	1.5	6
Nov-21	5,004	68	1.4	1
Dec-21	29,196	127	0.4	0
Jan-22	125,597	406	0.3	0
Feb-22	16,264	143	0.9	0
Mar-22	8,594	55	0.6	0
Apr-22	9,344	42	0.4	0
*May-22	18,087	56	0.3	0
*Jun-22	18,744	31	0.2	0

^{*}Hospitalization and death data not complete due to data lags

Figure. COVID-19 cases among active duty service members and percentage of cases that were hospitalized, March 2020 – June 2022



Note: February 2020 is not shown due to the very small number of cases. Hospitalization data for May - June 2022 not complete due to data lags

- 12. Internally, DoD regularly updates its information concerning the number of vaccinations administered to the force and health impact of those who developed COVID-19 infections. Data through June 24, 2022 demonstrated that of the 665,332 COVID-19 cases within the DoD, 6,321 individuals were hospitalized and 689 have died, including 96 military service members (service members include Active Duty, Reserves, and National Guard personnel). In both the civilian sector and in the military, the overwhelming majority of individuals hospitalized or who died were unvaccinated or not fully vaccinated.
- 13. The bed capacity at DoD's military medical treatment facilities (MTFs) has generally followed local civilian hospital utilization, with some MTFs having high admission rates and a need to temporarily curtail medical services. Throughout the pandemic, the National Guard has been called on extensively to provide medical support to the civilian population. During the winter months, DoD had increasingly been deploying military doctors, nurses, paramedics and

other personnel to U.S hospitals to assist in preventing the country's medical system from collapsing from demand.

Vaccine Impacts

- 14. Immunizations are a global health and development success story, saving millions of lives across the age spectrum annually from illness, chronic conditions, and potentially death. Immunizations provide benefit at both the individual and community level. First, by stimulating an active immune response, vaccinated individuals are largely protected from serious outcomes associated with the disease of concern. Second, when a high proportion of individuals are immune (i.e., herd immunity) human-to-human transmission is disrupted, thereby protecting those who remain susceptible (i.e., those who may not be able to receive a vaccine or do not mount an adequate antibody response). Disease prevention through immunization also mitigates the need for pharmacologic treatment, reducing the risk of drug-drug interactions or adverse reactions to the treatment.
- 15. A key component of primary health care, the U.S. Food and Drug Administration (FDA) provides regulatory allowance for immunizations and has licensed vaccines for over 20 different infectious diseases. The Advisory Committee on Immunization Practices (ACIP), an advisory committee of the CDC, develops recommendations on how to use vaccines to control diseases in the United States. The military also maintains awareness, surveillance, and provides guidance to DoD personnel and beneficiaries on vaccine-preventable diseases in the global setting.
- 16. The COVID-19 vaccines developed using mRNA technology have resulted in several inaccurate claims.
 - An initial claim is that mRNA vaccine clinical trials have never been studied in humans prior the implementation of mRNA COVID-19 vaccines. However, mRNA

vaccines are and have been in various clinical trial phases for diseases such as influenza, Zika, rabies, and cytomegalovirus, with the earliest study starting in 2013 (rabies). ²¹ The consideration of mRNA technology use continues to expand. In March 2022, the National Institutes of Health launched a clinical vaccine trial using mRNA technology for those with Human Immunodeficiency Virus (HIV). ²² Outside of vaccines for infectious diseases, lipid nanoparticle-mRNA vaccines are also in clinical trials for those with certain cancers, such as melanoma, ovarian cancer, and breast cancer. ²³

- A second claim is that the mRNA in the COVID-19 vaccines can alter our DNA. The COVID-19 vaccine mRNA is encased in a lipid nanoparticle which is taken up by the cell. The mRNA is then translated to a protein for recognition by our immune system in the cytoplasm of the cell. DNA is not found in the cytoplasm it's in the nucleus of the cell. For mRNA to get into the nucleus, it has to cross the nuclear membrane but it does not have a nuclear access signal to do so.²⁴
- A third claim is that COVID-19 vaccine mRNA technology is gene therapy, subject to different FDA safety requirements than what was conducted. However, the mRNA COVID-19 vaccines are not gene therapy. The companies Pfizer-BioNTech and Moderna developed their respective vaccines using a piece of genetic code from the SARS-CoV-2

²¹ https://clinicaltrials.gov/, last accessed July 7, 2022

²² https://www.nih.gov/news-events/news-releases/nih-launches-clinical-trial-three-mrna-hiv-vaccines, posted March 14, 2022.

²³https://clinicaltrials.gov/ct2/results?cond=cancer&term=mRNA+vaccines&cntry=&state=&city=&search=Search, last accessed July 6, 2022

 $^{^{24}}$ $\underline{\text{https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html}, \ last \ accessed \ July \ 7, \ 2022$

virus to elicit an immune response in recipients. This is not the same thing as gene therapy, which restructures nucleic acids (DNA and RNA) to (potentially) cure disease. In gene therapy, a faulty gene is replaced with a functional gene. This is not to say that gene therapy does not exist. Clinical trials of gene therapy have shown some success in treating certain diseases, such as severe combined immune deficiency (i.e. "bubble boy" disease), hemophilia, and leukemia. Vaccines that use mRNA technology are not gene therapies because they do not alter a person's genes. A February 2022 study which reported the ability to reverse transcribe the Pfizer COVID-19 mRNA vaccine *in vitro* into a human liver cell line²⁵ followed a May 2021 study by Zhang who reported that SARS-CoV-2 RNA (from the disease, not the vaccine) can be reverse transcribed and integrated into the genome of human cells.²⁶ The study design by Zhang and colleagues was challenged and to date his findings have not yet been duplicated.^{27,28} The study by Alden, who suggests that the Pfizer COVID-19 mRNA vaccine could be reverse transcribed in to the human

²⁵ Alden M, et al. Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. *Curr. Issues Mol. Biol.* 2022, 44, 1115-1126. https://doi.org/10.3390/cimb44030073.

²⁶ Zhang L, et al. Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues. *Proc. Natl. Acad. Sci.* USA 2021, 118, e2105968118. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8166107/pdf/pnas.202105968.pdf.

²⁷ Parry R., et al. No evidence of SARS-CoV-2 reverse transcription and integration as the origin of chimeric transcripts in patient tissues, *Proc. Natl. Acad. Sci* 118 (33) e2109066118, August 3, 2021 https://www.pnas.org/doi/10.1073/pnas.2109066118.

²⁸ Kazachenka A, and Kassiotis G. SARS-CoV-2 Host Chimeric RNA-Sequencing Reads to Not Necessarily Arise From Visru Integration Into the Host DNA *Front. Microbiol.*, 02 June 2021 | https://doi.org/10.3389/fmicb.2021.676693.

liver cell line, was quickly challenged as well.²⁹ First, the study involved a liver cancer cell line, which is not representative of normal cells. Additionally, the amount of vaccine used in the experiment (2 mcg/mL of vaccine to 200,000 cells) is far higher than the amount of vaccine adults receive through the vaccination (30 mcg/dose to the individual, made up of trillions of cells). Next, the study does not show evidence of uptake in the nucleus, where DNA is located. Rather, uptake was only seen in the cytoplasm (which is outside the nucleus). In summary, there is no evidence that mRNA COVID-19 vaccine alter a person's genes.

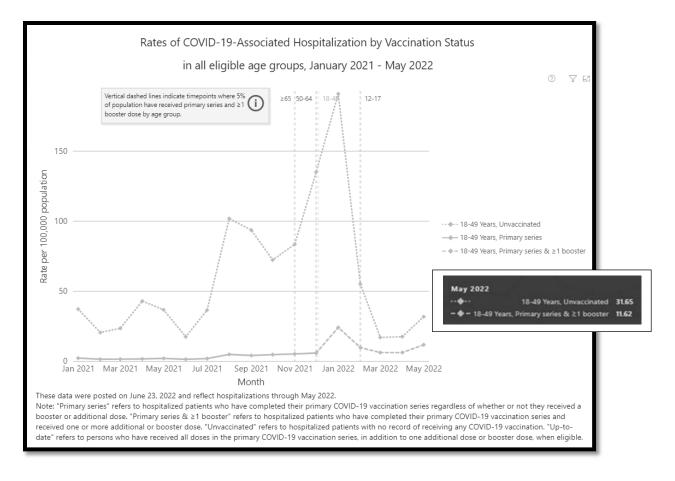
17. According to the CDC, over 596 million doses of COVID-19 vaccine have been given in the United States from December 14, 2020, through June 29, 2022.³⁰ Evidence consistently shows that the incidence of COVID-19-associated hospitalizations and deaths are higher in unvaccinated than vaccinated persons, even in Omicron predominance. In May 2022, , the rate of COVID-19 associated hospitalizations in unvaccinated 18-49 year olds was 31.6 per 100,000 and the rate of COVID-19 associated hospitalization in those who received primary series and at least one booster was 11.6 per 100,000.³¹

²⁹ Merchant HA, Comment on Aldén et al. Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. *Curr. Issues Mol. Biol.* 2022,44, 1115–1126

https://safe.menlosecurity.com/doc/docview/viewer/docN754220A02DC32e462aaa249407362c1dc12a6e06fe2cbeb2a5768306187446bfe7510b679f45

³⁰ https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html, last accessed July 7, 2022.

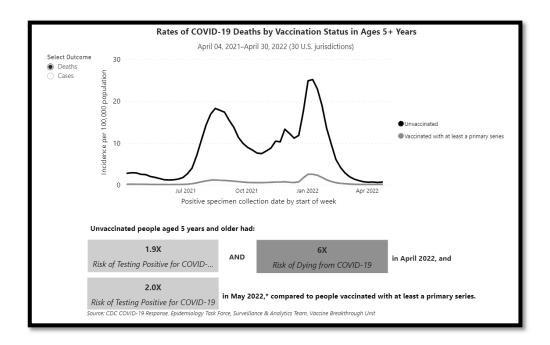
³¹ https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination, last accessed July 7, 2022.

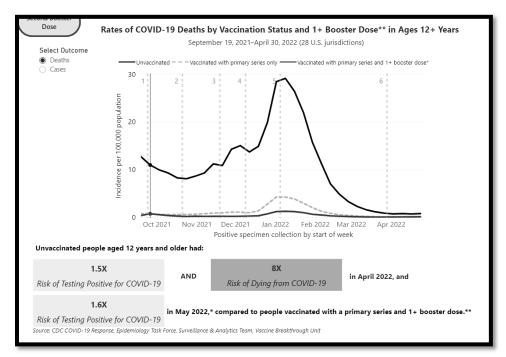


According to CDC, in April 2022 unvaccinated persons 5 years of age and older had a 1.9 times greater risk of testing positive for COVID-19 and a 6 times greater risk of dying from COVID-19 compared to people vaccinated with at least a primary series, and unvaccinated persons 12 years of age and older had a 1.5 times greater risk of testing positive for COVID-19 and 8 times greater risk of dying from COVID-19 compared to people vaccinated with a primary series and 1+ booster dose. In May2022, unvaccinated persons aged 5 years and older had a 2.0 times greater risk of testing positive for COVID-19 compared to people vaccinated with at least the primary series and

³² https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status, last accessed July 7, 2022.

those unvaccinated persons 12 years of age and older had a 1.6 times greater risk of testing positive for COVID-19 compared to people vaccinated with a primary series and 1+ booster dose.³³





³³ *Id*.

- 18. As of July 6, 2022, DoD immunization sites have administered over 7.9 million doses of COVID-19 vaccine. Adverse events temporally associated with vaccine administration are centrally captured by CDC and FDA's Vaccine Adverse Event Reporting System (VAERS) through passive surveillance, meaning that information is voluntarily reported by health care providers and the public. VAERS is not designed to determine whether a vaccine caused a health issue of concern, but it is useful for detecting unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. As of May 27, 2022, a total of 8,985 unique VAERS reports associated with COVID-19 vaccine (approximately 11 VAERS reports/10,000 doses administered) were submitted by DoD beneficiaries or those authorized to receive vaccine from DoD. Note that the number of VAERS reports/10,000 doses administered for DoD beneficiaries is likely to be lower, as the denominator does not take into account beneficiaries who receive vaccine in the civilian sector though DoD would still receive their VAERS report if the submitter indicated military affiliation. Additionally, individuals who had an adverse event but did not submit a VAERS would not be known and therefore would not be counted. It must be stressed that a VAERS submission to the CDC does not mean that the vaccine of concern caused or contributed to the medical issue reported.
- 19. The DoD has received hundreds of thousands of Pfizer-BioNTech BLA-compliant, EUA-labeled COVID-19 vaccine doses and continues to use them. On May 20, 2022 Pfizer-BioNTech's Comirnaty-labeled vaccine became available for ordering. To date, DoD has received over 42,000 doses within its supply chain and there are no restrictions to ordering this product.
- 20. Approach to immunizations within DoD are outlined in DoD Instruction 6205.02, "DoD Immunization Program" dated June 19, 2019, which states that it is DoD policy that all DoD personnel and other beneficiaries required or eligible to receive immunizations will be offered

immunizations in accordance with recommendations from the CDC and its ACIP. Army Regulation 40-562, Navy Bureau of Medicine and Surgery Instruction 6230.15B, Air Force Instruction 48-110 IP, Coast Guard Commandants Instruction M6230.4G, "Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases," October 7, 2013, further states the Military Service policy concerning immunizations follows the recommendations of the CDC, ACIP, and the prescribing information on the manufacturer's package inserts, unless there is a military-relevant reason to do otherwise. This document also describes general examples of medical exemptions, which include "evidence of immunity based on serologic tests, documented infection, or similar circumstances." Some interpret this as a diagnosis of COVID-19 disease and/or results of a COVID-19 serologic test means that a medical exemption should be granted. However, of significance is the phrase "evidence of immunity." CDC defines immunity as "protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected."³⁴ There are two major types of testing available for COVID-19: diagnostic tests, which assess for current infection, and antibody tests, which assess for antibody production, which is indicative of past infection and (in some tests) a history of vaccination. The FDA states, "Antibody tests should not be used to diagnose a current SARS-CoV-2 infection or COVID-19 and, at this time, should also not be used to check for immunity. More research is needed to determine what, if anything, antibody tests can tell us about a person's immunity."³⁵ As described below, the manufacturers of the lab tests also state that it is unclear at this time if a

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³⁴ https://www.cdc.gov/healthyschools/bam/diseases/vaccine-basics.htm, last accessed July 7, 2022.

 $^{^{35}\} https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics, last accessed July 7, 2022.$

positive antibody result infers immunity against future COVID-19 infection. Therefore, given the scientific evidence available, a medical exemption based on the history of COVID-19 disease or serology results does not meet "evidence of immunity." The presence of antibodies is not the same thing as being immune.

- 21. The CDC states that "COVID-19 vaccination is recommended for everyone ages 6 months and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection. This includes people with prolonged post-COVID-19 symptoms and applies to primary series doses and booster doses. This recommendation also applies to people who experience SARS-CoV-2 infection before or after receiving any COVID-19 dose. Growing epidemiologic evidence indicates that vaccination following infection further increases protection from subsequent infection and hospitalization, including in the setting of increased circulation of more infectious SARS-CoV-2 strains...Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making." 36
- 22. Further, CDC states "antibody testing is not currently recommended to assess the need for vaccination in an unvaccinated person or to assess immunity to SARS-CoV-2 following COVID-19 vaccination. If antibody testing was done, vaccination with the primary series, an additional dose, or a booster dose should be completed as recommended regardless of the antibody test result. SARS-CoV-2 antibody tests currently authorized under an Emergency Use Authorization have variable performance characteristics and limitations. Furthermore, serologic

³⁶ https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html, last accessed July 7, 2022.

correlates of protection have not been established and antibody testing does not evaluate the cellular immune response."³⁷

- 23. Although natural infection for some diseases, in some cases, can result in long-standing immunity (e.g., measles), there is risk of untoward outcomes from the disease itself, which can be chronic or even fatal. Examples include Pneumonia or invasive group B Strep from chickenpox, meningitis or epiglottitis from *Haemophilis influenza* type B, birth defects from rubella, liver cancer from Hepatitis B, and death from measles.
- 24. Examples of natural infections that do not mount long-standing immunity include, in addition to COVID-19, Influenza, Respiratory Syncytial Virus, Malaria, Whooping cough, and rotavirus. In other words, re-infection is possible. Multiple serotypes of a pathogen like what is seen with influenza, and likely with the COVID-19 variants, also make determination of a protective serologic level more difficult, especially to say there is lifelong immunity.
- 25. "Herd immunity" is an epidemiologic concept that explains how a community may be protected from an infectious disease that is human-to-human transmitted.^{38,39} Herd immunity can be achieved through vaccination or through natural infection, if enough individuals 1) survive the disease and 2) mount a life-long immune response. Safe and effective vaccines are unequivocally considered the safer approach to a vaccine-preventable disease as compared to the

³⁷ *Id*.

³⁸ Desai AN, Majumder MS. What Is Herd Immunity? *Journal of American Medical Association*. 2020;324(20):2113. doi:10.1001/jama.2020.20895.

³⁹ McDermott A. Core Concept: Herd Immunity is an Important-and Often Misunderstood-Public Health Phenomenon. *Proc Natl Acad Sci U S A*. 2021;118(21):e2107692118. doi:10.1073/pnas.2107692118.

unpredictable response that an individual may have to exposure to disease, as described above. When a large proportion of a community is immune, vulnerable members of the community are indirectly protected because their chance of infection exposure is very low. Herd immunity does not eliminate risk, but the phenomenon means that population risk is greatly reduced. Herd immunity is only possible when humans are the only source of infection transmission, when immunity can be clearly established to prevent lifelong infection and transmission, and when an adequate proportion of the population can safely develop immunity to protect all others. Barriers to classical herd immunity with COVID-19 include frequent mutations in the SARS-CoV-2 virus, asymptomatic transmission, limited duration of protection provided by infection and/or vaccination, and resistance to vaccination in addition to other public health efforts. 40 Measles (rubeola virus infection) is a classic example of the successful application of the concept of herd immunity. It is important to recognize that there is no disease where a successful vaccination program would cease once a certain level of immunity is reached, unless the disease is considered eradicated (i.e. smallpox in humans). The CDC recommends children continue to receive routine immunizations for diseases that we have not seen in this country for many years (i.e., polio) or rarely see (i.e. epiglottitis from *Haemophilus influenza*) so the vaccine preventable disease does not resurge. The Department of Defense vaccine program follows these same principles.

26. The percentage of the population needing to be immune to drive herd immunity varies from disease to disease. Generally, the more contagious a disease is, the greater proportion of the population needs to be immune to stop its spread. For example, with regards to the highly contagious measles disease, approximately 95% immunity within a population is needed to

⁴⁰ Morens DM, et al. The Concept of Classical Herd Immunity May Not Apply to COVID-19. *The Journal of Infectious Diseases* 2022; jiac109, https://doi.org/10.1093/infdis/jiac109

interrupt the chain of transmission. When the immunity levels of a population falls, local outbreaks can, and have, occurred. In 2019, 1,282 individual cases of measles were confirmed in 31 states, the highest level since 1992. The majority of those cases were among those who were not vaccinated. 41,42

27. The herd immunity threshold – the level above which the spread of disease will decline – is currently unknown for COVID-19. As described above, in order to interpret an immunological (antibody or cellular) response from disease or vaccination through testing, a correlate of protection (CoP) must be determined and validated. No FDA antibody test has validated a correlate of protection at this time and none of them are licensed. At present, there are no commercially available COVID-19 tests to assess cellular response. A systematic review of 25 articles on whether a humoral (antibody) correlate of protection exists for SARS-CoV-2 was published in April 2022. The authors concluded "mixed evidence regarding a SARS-CoV-2 CoP, with a lack of standardization between laboratory methodology, assay targets, and sampling time points complicating comparisons and interpretation...individual-level data provided contradictory findings (those with high antibody levels may still be reinfected)."⁴³ Nonetheless, it is generally agreed that the more severe the COVID-19 disease is in an individual, the more antibodies a survivor would produce and therefore likely would have a higher degree of protection and possibly be protected longer than those who are asymptomatic or with mild symptoms.

⁴¹ https://www.cdc.gov/measles/cases-outbreaks.html, last accessed July 7, 2022.

⁴² National Update on Measles Cases and Outbreaks — United States, January 1–October 1, 2019. Vol 68 No 40 https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6840e2-H.pdf

⁴³ Perry J, et al. Does a humoral correlate of protection exist for SARS-CoV-2? A systematic review. PLoS ONE 17(4): e0266852 https://doi.org/10.1371/journal.pone.026685

- 28. Those who receive the COVID-19 vaccine contribute to the information available from studying the outcomes from 596 million doses administered in the US and over the 12.1 billion doses administered globally. Antibody response to vaccination is more consistent and there is minimal risk compared to the potential long-term complications and treatments needed to manage COVID-19 disease and its consequences. Although breakthrough infections do occur depending on the circulating variant and the longer the interval from vaccination, COVID-19 vaccines (especially when indicated boosters are received) remain highly effective in preventing hospitalizations and death.
- 29. Debate continues about whether natural immunity versus vaccine-induced immunity is more safe and protective against outcomes from breakthrough infections (a reinfection in someone who was previously infected or an infection in a previously not infected individual who was immunized). A retrospective study from Israel during a period of Delta dominance found that the rates of SARS-CoV-2 breakthrough infections in Pfizer-BioNTech vaccinated individuals, while very low (highest rate = 1.5%), were 13 times higher than the rates of reinfection and hospitalization in previously infected individuals, though there was a statistically higher number of individuals in the vaccinated group over age 60 years. ⁴⁶ However,

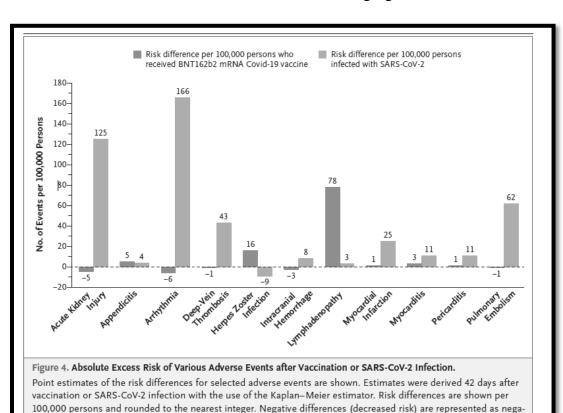
⁴⁴ https://ourworldindata.org/covid-vaccinations?country=OWID_WRL, last accessed July 7, 2022.

⁴⁵ Ferdinands JM, et al. Waning 2-Dose and 3-Dose Effectiveness of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance – VISION Network, 10 States, August 2021-January 2022, https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e2.html.

⁴⁶Gazit S, Shlezinger R et al. SARS-CoV-2 Naturally Acquired Immunity vs Vaccine-induced Immunity, Reinfections versus Breakthrough Infections: a Retrospective Cohort Study. Clin Infect Dis . 2022 Apr 5;ciac262. doi: 10.1093/cid/ciac262

an observational study,⁴⁷ also out of Israel, compared adverse events in 884,828 Pfizer-BioNTech vaccinated matched unvaccinated individuals in addition to comparing those who had a history of COVID-19 disease versus those who did not. As previously identified in multiple studies, vaccination with an mRNA vaccine like Pfizer-BioNTech was associated with an elevated risk of myocarditis compared to those unvaccinated (risk difference 2.7 events/100,000 people). However, when assessing the relative risk in those with a history of COVID-19 disease with those who did not have disease, the risk of myocarditis was substantially higher in those who had COVID-19 disease (risk difference of 11 events/100,000 persons). Additional comparisons between adverse events following COVID-19 vaccine and complications following

 $^{^{47}}$ Barda N, et al. Safety of the BNT162b2 mRNA COVID-19 Vaccine in a Nationwide Setting *N Engl J Med* 2021; 385:1078-1090.



tive values on the y axis, and positive differences (increased risk) are represented as positive values on the y axis.

The abbreviation mRNA denotes messenger RNA.

COVID-19 disease can also be observed in the following figure.

The Omicron variant

30. On November 26, 2021, the World Health Organization (WHO) designated the Omicron variant (Pango lineage B.1.1.529), first identified in November 2021 in Botswana and South Africa, a "variant of concern" upon recommendations of the Technical Advisory Group on SARS-CoV-2 Virus Evolution, which assesses if specific mutations and combinations of mutations alter the behavior of the virus.⁴⁸ The United States designated Omicron as a variant of

⁴⁸ https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern, posted November 26, 2021.

concern on November 30, 2021, and following first detection in the United States on December 1, 2021, it has been found to spread more easily than the original and Delta variants. ⁴⁹ Those infected with the Omicron variant in South Africa were initially reported in the media as not having severe outcomes and therefore concluding that this would be a "mild" variant. In attempt to address that misconception, on January 6, 2022, Dr. Tedros Adhanom Ghebreyesus, the WHO Director-General, stated that "while Omicron does appear to be less severe compared to Delta, especially in those vaccinated, it does not mean it should be categorized as 'mild'. Hospitals are becoming overcrowded and understaffed, which further results in preventable deaths from not only COVID-19 but other diseases and injuries where patients cannot receive timely care. First-generation vaccines may not stop all infections and transmission but they remain highly effective in reducing hospitalization and death from this virus."⁵⁰

31. Compared to the other COVID-19 variants of concern (Alpha, Beta, Gamma, and Delta), the Omicron variant is the most highly mutated strain, with at least 50 mutations within the genome and at least 32 mutations in the spike protein alone. This can result in increased infectivity and immune escape of the Omicron variant compared with the early wild-type strain and the other four variants of concern.⁵¹ The receptor binding domain (RBD) of the spike protein is what the virus uses to bind to our cells and initiate viral infection process. Antibodies produced from previous infection or vaccination, as well as the monoclonal antibodies (mAb) given to treat those

 $^{^{49}\} https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html, last accessed July 7, 2022.$

⁵⁰ https://twitter.com/WHO/status/1479167003109859328, posted January 6, 2022.

⁵¹ Tian D The emergence and epidemic characteristics of the highly mutated SARS-CoV-2 Omicron variant J Med Virol. 2022 Jun;94(6):2376-2383. doi: 10.1002/jmv.27643. Epub 2022 Feb 11.

infected, target the RBD. The degree to which antibodies bind or "neutralize" the virus determines the degree of resultant illness – the better antibodies bind, the less likely a person will become ill. This is why any mutation on the Spike protein RBD would cause concerns about the efficacy of existing vaccines, protection from previous infection, and the mAb given to treat people in preventing Omicron infection.

32. Multiple investigators turned their attention to assessing antibody effectiveness against the Omicron variant in COVID-19 disease survivors compared to vaccine recipients. One study assessed the neutralization of 9 monoclonal antibodies (mAb), sera from 34 COVID-19 vaccine (Pfizer or Astra Zeneca) primary series recipients who had not previously been infected, sera from 20 recipients who had received a Pfizer-BioNTech booster dose, and sera from 40 convalescent sera (blood serum obtained from individuals who had a history of infection) donors, 22 of whom had also been vaccinated.⁵² The better the neutralization, the better the protection. Results showed that the Omicron variant was totally or partially resistant to neutralization by all mAbs tested. Sera from those vaccinated, sampled 5 months after being fully vaccinated, had limited inhibition of the Omicron variant. Blood sera from those with a history of COVID-19 disease demonstrated no or low neutralizing activity against Omicron. Those who received a booster COVID-19 vaccine dose did generate an anti-Omicron neutralizing response, though lower than what has been seen against the Delta variant. A second study⁵³ also demonstrated that those

⁵² Planas, D. et al. Considerable escape of SARS-CoV-2 Omicron to antibody neutralization. *Nature* https://doi.org/10.1038/s41586-021-04389-z (2021).

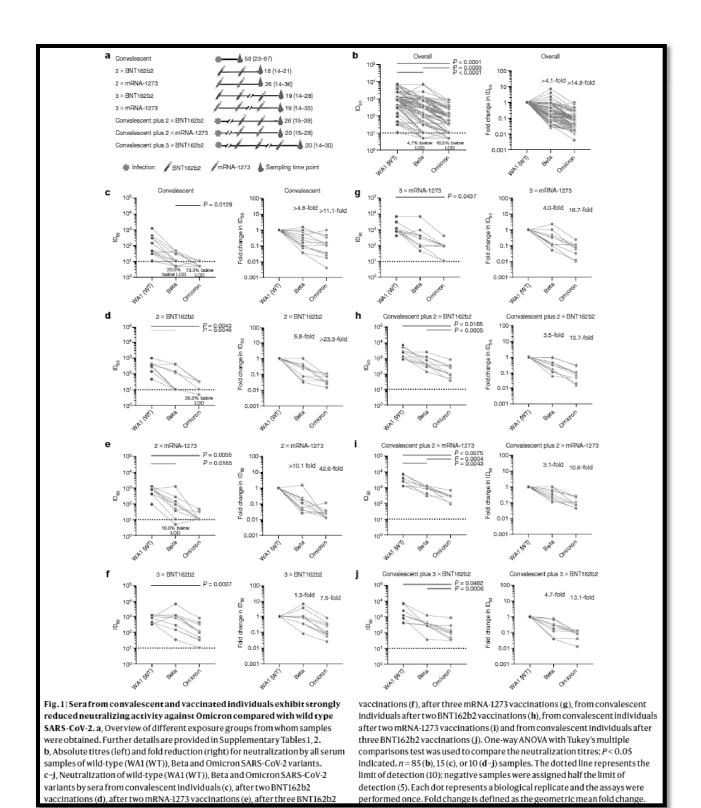
⁵³ Rossler A., et al SARS-CoV-2 Omicron Variant Neutralization in Serum from Vaccinated and Convalescent Persons, *N Engl J Med* 2022; 386:698-700https://www.nejm.org/doi/full/10.1056/NEJMc2119236.

who had a history of infection and were fully vaccinated (whether disease then vaccinated or vaccinated then disease (i.e., a breakthrough infection) were better able to neutralize the Omicron variant as compared to those who had only a history of disease or had a history of being fully An additional small study investigated the neutralizing activity of sera from convalescent patients, mRNA double vaccinated (BNT162b2 = Pfizer-BioNTech; mRNA-1273 = Moderna), mRNA boosted, convalescent double vaccinated, and convalescent boosted individuals against the original SARS-CoV-2 strain, Beta variant (B.1.351), and Omicron (B1.1.529) variant in a laboratory (in vitro) setting.⁵⁴ In the figures depicted below, Figures 1c–1j provide the results of different combinations of sera studied. What would be interpreted as the "best" combination to work against the Omicron variant is the highest level of red dots on the y-axis seen with the "Omicron" on the x-axis. For example, Figure 1c shows the results of those individuals with a history of COVID-19 disease. In an oversimplified interpretation, Figure 1c shows that those with a history of COVID-19 disease had no measurable neutralizing activity against the Omicron variant. In Figures 1d and 1e, (2 doses of either Pfizer-BioNTech or Moderna), there is some neutralization against Omicron. Those who received a booster (Figure 1f and 1g) had higher levels of neutralization against Omicron compared to the two-dose primary series. Those who had a history of disease and were then vaccinated with a two-dose primary series or a two-dose primary series and a booster (Figures 1h-1j) had better Omicron neutralization. In summary, the study found that neutralizing activity against Omicron "is most impacted in unvaccinated, convalescent individuals and in naïve individuals who acquired immunity through two mRNA COVID-19

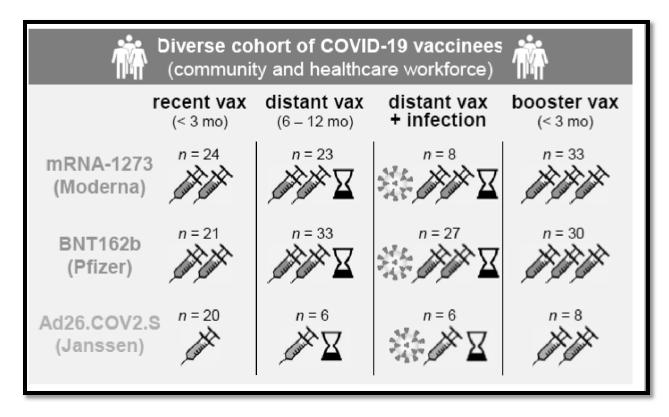
⁵⁴ Carreño, J.M., Alshammary, H., Tcheou, J. *et al.* Activity of convalescent and vaccine serum against SARS-CoV-2 Omicron. *Nature* 602, 682–688 (2022). https://doi.org/10.1038/s41586-022-04399-5 https://www.nature.com/articles/s41586-022-04399-5.

vaccine doses" and that "boosted individuals had, at least within the short time after the booster dose, significant protection against symptomatic disease in the range of 75%." 55

⁵⁵ *Id.* at 2.

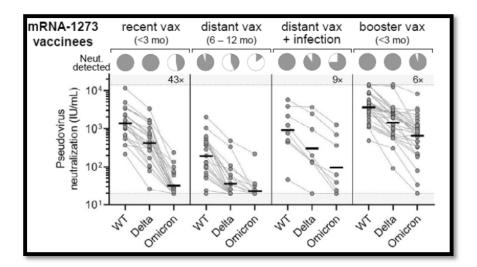


33. An additional study⁵⁶ assessed the neutralizing potency of sera from 88 mRNA-1273 (Moderna), 111 BNT162b (Pfizer-BioNTech), and 40 Ad26.COV2.S (Janssen) vaccine recipients against wild-type, Delta, and Omicron COVID-19 variants, based on recent vaccination (< 3 months), distant vaccination (6-12 months), history of infection and distant vaccination, and recent booster vaccination (< 3 months), as depicted below.

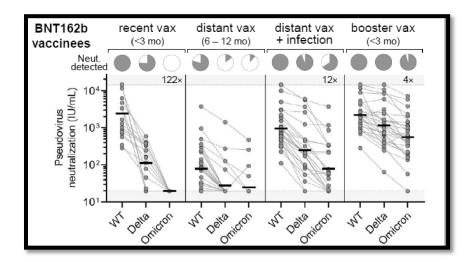


34. Against the Omicron variant, recent (< 3 months) Moderna vaccine recipients exhibited a 43-fold lower neutralization than against the wild type (WT) strain. Those with a history of vaccination and infection had a 9-fold decrease in neutralization than WT, whereas those who received a booster dose less than 3 months ago had a 6-fold decrease in neutralization compared to WT.

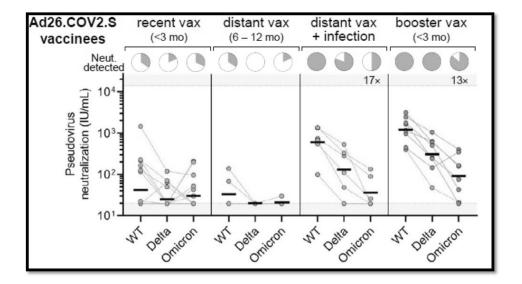
⁵⁶ Garcia-Beltran WF, et al mRNA-based COVID-19 vaccine boosters induce neutralizing immunity against SARS-CoV-2 Omicron variant. *Cell* 2022 Feb 3;185(3):457-466.e4. doi: 10.1016/j.cell.2021.12.033.



35. Similar results were seen in Pfizer-BioNTech recipients, with the best protection against Omicron seen in those who recently received a booster dose.



36. Of the three vaccines, Janssen recipients had the least neutralization against the Omicron variant, with those who recently received a booster dose demonstrating a 13-fold decrease in neutralization as compared to the WT.



37. Finally, two CDC publications described vaccine effectiveness during periods of Delta and Omicron dominance. The first study evaluated the benefit of a third COVID-19 vaccine dose in those who were and were not immunocompromised between August and December 2021. In those who were not immunocompromised vs immunocompromised, vaccine effectiveness (VE) was 82% and 69%, respectively, in those who were fully vaccinated and 97% and 88%, respectively in those who had received 3 doses of COVID-19 vaccine.⁵⁷ The second publication reported on the waning 2- and 3-dose effectiveness of mRNA vaccines against COVID-19 associated emergency department (ED) and urgent care (UC) encounters and hospitalizations among adults during Delta and Omicron between August 2021 and January 2022. During the Delta period, those who sought ED or UC care and received 2 doses versus 3 doses of a mRNA vaccine had an overall VE of 80% and 96%, respectively. Of those admitted to the hospital, COVID-19 VE was 85% and 95%, respectively. During the Omicron period, those who sought

⁵⁷ Tenforde MW, et al., Effectiveness of a Third Dose of Pfizer-BioNTech and Moderna Vaccines in Preventing COVID-19 Hospitalization Among Immunocompetent and Immunocompromised Adults – United States, August-December 2021 Morb Mortal. Wkly Rep 2022;71(4):118-121. DOI:https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a2.htm.

ED or UC care and received 2 doses versus 3 doses of a mRNA vaccine had an overall VE of 41% and 83%, respectively. Those who were admitted to the hospital demonstrated overall VE of 55% and 88%, respectively⁵⁸. Although there was a noticeable decrease in VE during the Omicron period, comparatively mRNA COVID-19 VE is higher than annual influenza vaccine, where VE has ranged between 29-48% over the last 5 seasons.⁵⁹

38. In contrast to the above studies, the CDC recently published a study examining the impact of primary COVID-19 vaccination and previous SARS-CoV-2 infection on COVID-19 incidence and hospitalization rates from California and New York. The findings demonstrated that prior to Delta variant, being vaccinated with or without a history of COVID-19 resulted in lower incidence of laboratory-confirmed COVID-19 disease and hospitalizations as compared to those who were unvaccinated with a history of disease. However, after the Delta variant became dominant, those with a history of COVID-19 disease, with or without a history of vaccination, had a lower incidence of laboratory-confirmed COVID-19 disease than those who were vaccinated without a history of COVID-19. Excluded in the study was discussion of severity of COVID-19 disease and outcomes of those who had disease (complications, etc.). CDC concludes with reminding readers that more than 130,000 California and New York residents died from COVID-

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⁵⁸ Ferdinands JM, et al. Waning 2-Dose and 3-Dose Effectiveness of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance – VISION Network, 10 States, August 2021-January 2022. Morb Mortal. Wkly Rep 2022;71:1-9. DOI: https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e2.htm.

⁵⁹ https://www.cdc.gov/flu/vaccines-work/past-seasons-estimates.html, last accessed July 7, 2022.

⁶⁰ Leon TM, Dorabawila V., Nelso L, et al. COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis – California and New York, May-November 2021. Morb Mortal. Wkly Rep 2022;71:125-131. DOI: http://dx.doi.org/10.15585/mmwr.mm7104e1.

19 through November 30, 2021, and that "vaccination remains the safest and primary strategy to prevent SARS-CoV-2 infections, associated complications, and onward transmission." Moreover, a recent analysis of data from a multistate hospital network on severe COVID-19 outcomes during the Alpha, Delta, and Omicron waves found that "receipt of 2 or 3 doses of a COVID-19 mRNA vaccine conferred 90% protection against COVID-19 associated invasive mechanical ventilation (IMV) or in-hospital death among adults... Among immunocompetent adults with no chronic medical conditions, vaccine efficacy for 2 or 3 doses was 98%... Protection against IMV or death was consistent throughout the Delta and Omicron periods and was higher in adults who received a third vaccine dose, including 94% during the Omicron period." ⁶¹

39. Unvaccinated persons without a history of COVID-19 are most vulnerable to COVID-19 disease. Vaccination was highly effective against the initial SARS-CoV-2 strain it was developed to protect against and continues to be protective against severe disease, hospitalization, and death. The longer the interval from vaccination or natural infection, the increased risk for breakthrough disease. Vaccination and a history of disease was shown to be less protective than vaccination and booster dose against both the Delta and Omicron variants. CDC states "primary COVID-19 vaccination, additional doses, and booster doses are recommended by CDC's Advisory Committee on Immunization Practices to ensure that all eligible persons are up to date with COVID-19 vaccine, which provides the most robust protection against initial infection, severe illness, hospitalization, long-term sequelae, and death."

⁶¹ Mark W. Tenforde, MD, et al. Effectiveness of mRNA Vaccination in Preventing COVID-19-Associated Inveasive Mechanical Ventialation and Death – United States, March 2021–January 2022. MMWR Morb Mortal. Wkly Rep 2022; 71:459-465. Available at: https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7112e1-H.pdf.

⁶² Leon TM, Dorabawila V., Nelso L, et al. COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis – California and New York, May-

Risks from COVID-19 Vaccination

- 40. Risks from immunization, including COVID-19 vaccines are rare. CDC provides routine updates on specific adverse events temporally associated with COVID-19 vaccines.⁶³ CDC updates as of July 6, 2022, include the following:
 - A. **Anaphylaxis after COVID-19 vaccination is rare** and has occurred in approximately 5 people per million vaccinated in the United States.
 - B. Thrombosis with thrombocytopenia syndrome (TTS) after Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccination is rare and has occurred in approximately 4 cases per one million doses administered. TTS is a rare but serious adverse event that causes blood clots in large blood vessels and low platelets (blood cells that help form clots). A review of reports indicates a causal relationship between the J&J/Janssen COVID-19 vaccine and TTS.
 - C. Guillain-Barre (GBS) in people who have received the J&J/Janssen COVID-19 vaccine is rare. GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. Most people fully recover from GBS, but some have permanent nerve damage. GBS has largely been reported in men ages 50 years and older. Based on a recent analysis of data from the Vaccine Safety Datalink, the rate of GBS within the first 21 days following J&J/Janssen COVID-19 vaccination was found to be 21 times higher than after Pfizer-

November 2021. MMWR Morb Mortal. Wkly Rep 2022;71:125-131. January 28, 2022 http://dx.doi.org/10.15585/mmwr.mm7104e1.

⁶³ https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html, last accessed July 7, 2022.

BioNTech or Moderna (mRNA COVID-19 vaccines). After the first 42 days, the rate of GBS was 11 times higher following J&J/Janssen COVID-19 vaccination. The analysis found no increased risk of GBS after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines).

- D. Myocarditis and pericarditis after COVID-19 vaccination are rare. Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the outer lining of the heart. Most patients with myocarditis or pericarditis after COVID-19 vaccination responded well to medicine and rest and felt better quickly. Most cases have been reported after receiving Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines), particularly in male adolescents and young adults. A review of vaccine safety data in VAERS from December 2020–August 2021 found a small but increased risk of myocarditis after mRNA COVID-19 vaccines. Over 350 million mRNA vaccines were given during the study period and CDC scientists found that rates of myocarditis were highest following the second dose of an mRNA vaccine among males in the following age groups:
 - 12–15 years (70.7 cases per one million doses of Pfizer-BioNTech)
 - 16–17 years (105.9 cases per one million doses of Pfizer-BioNTech)
 - 18–24 years (52.4 cases and 56.3 cases per million doses of Pfizer-BioNTech and Moderna, respectively)

As of June 30, 2022, there have been 1,011 reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of those, 261 remain under review. Through confirmation of symptoms and diagnostics by provider

interview or review of medical records, 659 reports have been verified. See the following for a breakdown of reports by age group.

- 5-11 years: 22 verified reports of myocarditis after 19,682,799 doses administered
- 12-15 years: 341 verified reports of myocarditis after 23,794,975 doses administered
- 16-17 years: 296 verified reports of myocarditis after 12,951,176 doses administered

Multiple studies and reviews of data from vaccine safety monitoring systems continue to show that vaccines are safe. As the COVID-19 vaccines are authorized for younger children, CDC and FDA will continue to monitor for and evaluate reports of myocarditis and pericarditis after COVID-19 vaccination and will share more information as it becomes available.

E. Reports of death after COVID-19 vaccination are rare. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. More than 596 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through June 29, 2022. During this time, VAERS received 15,312 preliminary reports of death (0.0026%) among people who received a COVID-19 vaccine. CDC and FDA clinicians review reports of death to VAERS including death certificates, autopsy, and medical records. Continued monitoring has identified nine deaths causally associated with J&J/JanssenCOVID-19 vaccination. CDC and FDA continue to review reports of

death following COVID-19 vaccination and update information as it becomes available.

41. Additionally, on October 27, 2021, the COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS) provided an updated statement regarding myocarditis and pericarditis reported with COVID-19 mRNA vaccines, stating, in part: The GACVS COVID-19 subcommittee notes that myocarditis can occur following SARS-CoV-2 infection (COVID-19 disease) and that mRNA vaccines have clear benefit in preventing hospitalisation and death from COVID-19.64 A follow up Joint Statement from the International Coalition of Medicines Regulatory Authorities and World Health Organization in May 2022 reiterates that "the benefit-risk of both of the (mRNA) vaccines remains positive". 65 In March 2022, Rosenblum, et al., published United States safety data captured by VAERS reports and vsafe, a new active surveillance system, during the first 6 months of the US COVID-19 vaccination program. During that time, a total of 340,522 VAERS reports were processed following administration of more than 298 million doses of mRNA COVID-19 vaccine. Of these VAERS reports, 313,499 (92.1%) were not serious and managed outside of the hospital setting, 22,527 (6.6%) were serious (defined as inpatient hospitalization, prolongation of hospitalization, permanent disability, life-threatening illness, congenital anomaly or birth defect) and 4,496 (1.3%) were deaths. Over half of the 4,914,583 v-safe participants self-reported local (i.e injection site pain) and systemic (i.e fever) symptoms, most commonly after dose two. COVID-19 vaccine

⁶⁴ https://www.who.int/news/item/27-10-2021-gacvs-statement-myocarditis-pericarditis-covid-19-mrna-vaccines-updated, last accessed June 9, 2022.

^{65 &}lt;u>https://www.who.int/news/item/17-05-2022-statement-for-healthcare-professionals-how-covid-19-vaccines-are-regulated-for-safety-and-effectiveness</u>, last accessed July 7, 2022.

safety monitoring has been the "most comprehensive in US history."⁶⁶ Most reported adverse events captured by VAERS or v-safe were mild and short in duration. The authors report that the mRNA COVID-19 vaccine post-authorization safety profile that was generally consistent with pre-authorization trials and early post-authorization surveillance reports. They conclude by stating "vaccines are the most effective tool to prevent serious COVID-19 disease outcomes and the benefits of immunisation in preventing serious morbidity and mortality strongly favour vaccination."⁶⁷

COVID-19 Antibody Tests

- 42. As described above, testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purposes of vaccine decision-making. Last updated June 14, 2022, the FDA's In vitro diagnostics EUAs Serology and Other Adaptive Immune Response Tests for SARS-CoV-2⁶⁸ lists approximately 85 products, of which all of them had one of the following three statements about immunity interpretation:
 - A. "You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection." 69

⁶⁶ Rosenblum HG., et al. Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to the Vaccine Adverse Event Reporting System and v-safe *Lancet Infect Dis.* 2022 Mar 7;S1473-3099(22)00054-8 https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00054-8/fulltext.

⁶⁷ *Id.*,

⁶⁸ https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2, last accessed July 7, 2022.

⁶⁹ https://www.fda.gov/media/146369/download, last accessed July 7, 2022.

- B. "It is unknown how long antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection. Incorrect assumptions of immunity may lead to premature discontinuation of physical distancing requirements and increase the risk of infection for individuals, their households and the public." ⁷⁰
- C. "It is unknown how long (IgA, IgM or IgG) antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection. A positive result for XXX test may not mean that an individual's current or past symptoms were due to COVID-19 infection."

The Continued Need for COVID-19 Vaccination

43. Decreasing COVID-19 infections, hospitalizations, and/or death trends, combined with the lifting of mask mandates, loosening of travel restrictions, and the desire to return to "normal" may indicate to some that there is no longer a need to mandate vaccination or to enforce it. To the contrary, vaccination as recommended by the CDC remains essential to protecting against serious illness, hospitalization, and death, is key to limiting the opportunities for the virus to mutate (thus causing new variants), and is necessary in reducing public risks that could require future safety measures such as travel restrictions and reinstituting public health measures. The COVID-19 landscape just in the past few weeks has tempered some of the excitement of an imminent pandemic exit as cases, hospitalizations, and death rates continue a slow, but steady climb. As a

⁷⁰ https://www.fda.gov/media/138627/download, last accessed July 7, 2022.

⁷¹ https://www.fda.gov/media/137542/download, last accessed July 7, 2022.

country, we are only 66.8% fully vaccinated and less than 50% of those fully vaccinated have received an indicated booster.⁷² .

- 44. On April 12, 2022, the Secretary of Health and Human Services renewed the determination that a public health emergency still exists.⁷³
- Although updated formulations of COVID-19 vaccines concerning more recent variants are undergoing clinical studies at present with encouraging preliminary results, most likely they will not be available, presuming efficacy and safety has been demonstrated to the FDA and CDC, until Fall/Winter 2022. Exiting the COVID-19 pandemic requires global commitment and medical preparedness, particularly in those whose responsibilities, like the military, take them around the world. The Ukraine conflict, where millions of displaced families are congregated in close quarters and under high stress are a prime source for not only COVID-19 infection and other diseases, are a nidus for new COVID-19 variant development and transmission threats to which our service members, and the partner-nation-forces they work with, will be exposed. The concern of the Omicron variant and subvariants is on full display as Beijing begins its first COVID-19 vaccine mandate on the mainland.⁷⁴ In the US, an increasing number of counties are categorized as having medium [38.1% (+2.64 from last week)] or high [20.73% (+1.26% from last week)] COVID community levels. Other countries are starting to see an uptick in cases as well.⁷⁵ The pandemic is not yet over. Accordingly, the DoD must utilize what is currently available to maintain

⁷² https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html, last accessed July 7, 2022.

⁷³ https://aspr.hhs.gov/legal/PHE/Pages/COVID19-12Apr2022.aspx, last accessed July 7, 2022

⁷⁴ https://www.cnn.com/2022/07/07/china/china-covid-beijing-vaccine-mandate-intl-hnk/index.html, last accessed July 7, 2022

⁷⁵ https://coronavirus.jhu.edu/data/new-cases, last accessed June 9, 2022.

the health of its population – and that includes vaccination, our safest most effective preventative

and protective measure against severe disease, hospitalization, and death.

46. I am aware that this declaration may be filed in multiple cases for the purpose of

defending the Secretary of Defense's directive to vaccinate Service members against the COVID-

.6I

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on July 10, 2022, in Falls Church, Virginia

Pigitally signed by RANS,TONYA,SUE,1081263031

RANS,TONYA,SUE,1081263031

Date: 2022.07.10 14:18:29 -04'00'

Tonya S. Rans Colonel, Medical Corps, U.S. Air Force Chief, Immunization Healthcare Division Public Health Directorate Falls Church, Virginia

Exhibit 3

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

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DECLARATION OF REAR ADMIRAL ERIC JONES

- I, REAR ADMIRAL ERIC C. JONES, hereby declare and state:
- 1. I am a commissioned officer serving on active duty in the United States Coast Guard. I have served in the Coast Guard for over thirty years. I am currently serving as the Deputy for Personnel Readiness, and I have served in this position since April 2022. Immediately prior to this assignment, I served as the Assistant Commandant for Human Resources. My prior assignments include a variety of assignments both afloat and ashore, including command afloat. I make this declaration in my official capacity, based upon my personal knowledge and upon information that has been provided to me in the course of my official duties.
- 2. As the Deputy for Personnel Readiness, I oversee the recruiting, development, and support of the highly capable and diverse workforce that enables Coast Guard mission success. In this capacity, I am responsible for supervising the human resources and force readiness training staffs

to assure a mission-ready workforce of over 57,000 active duty, reserve, and civilian personnel.

I. The COVID-19 Vaccine Mandate

- 3. On August 24, 2021, the Secretary of Defense determined "that mandatory vaccination against coronavirus disease 2019 (COVID-19) is necessary to protect the Force and defend the American people" and directed the "Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard, who are not fully vaccinated against COVID-19." The military services have a joint policy with regard to immunizations to prevent infectious diseases—Army Regulation 40-562, which is also Coast Guard Commandant Instruction Manual 6230.4G. Consequently, the Coast Guard quickly also took steps to achieve full vaccination of its military members.
- 4. On August 26, 2021, the Coast Guard mandated all Coast Guard active duty and Ready Reserve members who were not fully vaccinated to receive the Pfizer-BioNTech COVID-19 vaccine, or to otherwise achieve full vaccination through any vaccine administered under the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA), or a vaccine on the World Health Organization Emergency Use Listing.² The Coast Guard has issued supplemental guidance to this mandate in the months following the August 26, 2021, announcement.³
- 5. All Coast Guard commands were directed to counsel all unvaccinated Coast Guard military members regarding the requirement to get vaccinated, the timeline for vaccination, and the process

¹ Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members, 24 August 2021.

² COVID-19: Mandating COVID-19 Vaccination for Military Members, ALCOAST 305/21. In this directive, the Coast Guard noted that the "Pfizer-BioNTech COVID-19 was granted license by the Food and Drug Administration (FDA) on 23 Aug 2021." *Id.* ¶ 3.

³ ALCOAST 315/21, ALCOAST 352/21, ALCGPSC 104/21, ALCOAST 420/21, ALCOAST 446/21, ALCGPSC 016/22, ALCOAST 078/22, ALCOAST 131/22, ALCOAST 157/22.

to request medical exemption or religious accommodation.⁴ Coast Guard commands were required to document this initial counseling through Administrative Remarks Form, CG-3307. Commands were further directed to document the process by which members who continued to refuse to vaccinate were ordered to a vaccine administration site at a particular date and time designated by the command, and any subsequent failure by the member to abide by this order. ALCOAST 352/21.

- 6. Subsequent guidance notified members of the consequences of failure to vaccinate without an approved medical exemption or religious accommodation request. Members who refuse to vaccinate are ineligible to execute permanent change of station orders. ALCGPSC 016/22. They are ineligible for Command, full-time Command Master Chief/Senior Chief, or Reserve Command Master Chief/Senior Chief positions, and members currently serving in these positions may be relieved for cause. ALCOAST 446/21. Additionally, members who refuse to vaccinate may be subject to additional measures necessary to mitigate health risks to other members and the public, including restrictions on official travel, liberty (i.e. off-duty hours), and leave, and cancellation of "A" and "C" school orders and advanced education programs.⁵ ALCOAST 352/21; ALCOAST 157/22. Failure to obey a lawful order to vaccinate is also punishable under Article 92 of the Uniform Code of Military Justice (UCMJ) and may result in punitive or administrative action, including separation. ALCOAST 315/21.
- 7. Most recently, on July 22, 2022, the Coast Guard issued supplemental guidance beginning involuntary administrative separation processing for all non-compliant Active Duty service

⁴ ALCOAST 315/21. Members were directed to submit their religious accommodation requests no later than November 30, 2021. ALCOAST 420/21. If a member's medical exemption request or religious accommodation request is denied, members are directed to receive their first COVID-19 dose within ten (10) business days of notification of denial. ALCOAST 446/21.

⁵ "A" and "C" school orders direct members to attend temporary rate/job-specific training.

members, and initiating processing for involuntary transfer to the Inactive Status List (ISL) for all non-compliant Reserve members. ALCOAST 270/22.

8. Reassignment to the ISL is not a separation or discharge. A member on the ISL is still a member of the Coast Guard. The ISL includes former Active Duty and Reserve military personnel who, though not actively participating in the military, are still affiliated with the Reserve Component. The ISL serves as a resource pool of Reserve members who, if they meet readiness standards, may be eligible to return to the Selected Reserve in a participating status. Reserve members routinely transfer to and from the ISL in order to manage commitments in their personal lives (e.g., following the birth of a child). Reserve members who are involuntary transferred to the ISL will be placed in a no pay/no points status. Placing a member in a no pay/no points status on the ISL means that the member will not be drilling with the member's unit and thus will not be earning pay for that work or credit toward retirement. Barring misconduct, individuals who are transferred to the ISL and who complete their military service obligation are honorably discharged.

II. COVID-19 Exemption Request Processing

9. Members may seek exemption from the COVID-19 vaccination mandate. There are two types of exemptions from Coast Guard vaccination requirements: medical exemptions and administrative exemptions.

a. Medical Exemptions

10. Medical exemptions to vaccination requirements are governed by Army Regulation (AR) 40-562, which is a consolidated military services regulation implemented by the Coast Guard through Commandant Instruction Manual 6230.4G (hereinafter "CIM 6230.4G"). A medical exemption includes any medical contraindication relevant to a specific vaccine or other medication. Medical personnel are responsible for reviewing and granting medical exemptions.

CIM 6230.4G, 2-6. Health care providers will determine a medical exemption based on the health of the vaccine candidate and the nature of the immunization under consideration. CIM 6230.4G. Medical exemptions are revoked when they are no longer clinically warranted. *Id.*

11. All requests for medical exemptions are handled on a case-by-case basis. Healthcare providers consider the health of the candidate and the nature of the immunization under consideration. In doing do, healthcare providers are directed to refer to detailed guidance regarding vaccine medical contraindications and precautions, as well as required screening and evaluation of recipients.⁶

12. First, a military physician counsels the requester. Through this counseling, the physician ensures that the member is making an informed decision by addressing specific information about the diseases concerned; specific vaccine information including product constituents, benefits, and risks; and potential risks of infection incurred by unimmunized individuals. The member's command then counsels the individual concerning how noncompliance with immunization requirements may adversely impact the member's deployability, assignment, or international travel.

13. Unless granted an exception, risk mitigation measures, including restrictions on official travel, liberty (i.e. off-duty hours), and leave, and cancellation of "A" and "C" school orders and advanced education programs, remain in place regardless of whether a member's request for medical exemption is pending or approved. ALCGPSC 104/21.

i. Temporary Medical Exemptions

⁶ See ALCOAST COMDT Notice 089/21. This guidance includes CDC COVID-19 Vaccine Information Statements (VIS); FDA Emergency Use Authorization Fact Sheets for Healthcare Providers; CDC guidance on triage of people with a history of allergies or allergic reactions; and CDC ACIP Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States, including Ingredients included in COVID-19 vaccines.

14. The total number of temporary medical exemptions granted is not tracked. The present number is unknown because the amount of these active exemptions is constantly fluctuating, as they are related to a member's underlying health condition that is expected to resolve. Temporary medical exemptions to a COVID-19 vaccine have been granted, for example, to individuals who are actively ill with COVID-19 or another illness; pregnant individuals whose healthcare provider determined that it was appropriate to defer vaccination until later in pregnancy or post-pregnancy; and members who were actively enrolled in COVID-19 clinical trials, if any.

15. Temporary exemptions could be granted for as little as a day or up to 365 days, depending on a number of factors, including anticipated changes in a patient's medical condition or the need for further evaluation at a future time. The duration of a temporary exemption necessarily varies based on the medical conditions and history of the patient at the time of evaluation. For example, an exemption granted related to a pregnancy could be in effect only for the duration of the pregnancy. A member who is actively enrolled in COVID-19 clinical trials may be exempt from vaccination until their participation in the trial is complete. Healthcare providers work closely with their patients to evaluate whether or not to extend or cancel a temporary medical exemption. If the underlying condition resolves and no longer necessitates temporary medical exemption, the member will be counseled regarding the timeline for initiating vaccination against COVID-19.

16. The approval authority for temporary medical exemptions from the COVID-19 vaccination directive is the local military-employed or affiliated Medical Officer. The medical officer's decision is memorialized in a memo provided to the requester, and a reconsideration process is available through the Operational Medicine Division of the Health, Safety, and Work-Life Service Center.

ii. Permanent Medical Exemptions

17. The criteria for permanent exemption from COVID-19 vaccination are either severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or immediate allergic reaction of any severity to a previous dose, or diagnosed allergy to a component of the COVID-19 vaccine. ALCOAST COMDT Notice 089/21.

18. For permanent medical exemptions to any mandatory vaccine, including the COVID19 vaccine, requests are routed through a local Medical Officer, to the Commandant,
Operational Medicine and Quality Improvement Division (CG-1121), as final approval
authority. This centralized approval authority for permanent medical exemptions to the
vaccine requirements ensures uniformity in the adjudication of requests for exemption.
ALCOAST COMDT Notice 089/21. The final decision is memorialized in a memo, which
provides an explanation for the basis for the decision. No permanent medical exemptions have
been revoked.

b. Administrative Exemptions

19. Consistent with the other military services, Coast Guard policy also provides for administrative exemptions to vaccination requirements for non-medical reasons. *See* Commandant Instruction Manual 6230.4G, 2-6. Non-medical personnel (sometimes with the assistance of advising medical personnel) are responsible for reviewing and granting administrative exemptions. CIM 6230.4G, 2-6.

20. The Coast Guard has granted only two types of administrative exemptions to the COVID-19 vaccine. First, the Coast Guard has granted an administrative exemption to the vaccination mandate for all members with an approved separation or retirement date no later than October 1, 2022. ALCOAST 078/22. Apart from the administrative exemption for members with an approved separation or retirement date no later than October 1, 2022, and the religious

accommodation exemption mentioned below, no other types of administrative exemptions have been granted, nor are any other types contemplated.

i. Religious Accommodation Requests

- 21. Administrative exemptions also include requests to accommodate an individual service member's religious beliefs. Requests for religious accommodation are processed on a case-by-case basis in accordance with Military Religious Accommodations, Commandant Instruction 1000.15, 11(c)(3) ("CI1000.15").
- 22. Given its overall size and interlocking missions, the Coast Guard has centralized its review of religious accommodation requests for immunizations to ensure consistency and to assess the impact of accommodations Coast Guard—wide. However, there is no single policy or practice of approving or denying religious accommodation requests, including with respect to the COVID-19 vaccine.
- 23. The review of requests for religious accommodation is a multi-step process that involves assessing the individual member's request, including the impact to operations, to the member's unit, and to the Coast Guard as a whole. Because cases are evaluated individually, a decision on a member's request, including any subsequent appeal of a denial, may take several days to several months.
- 24. Each request is individually reviewed with regard to the nature and sincerity of the religious belief, the extent to which the vaccine requirement burdens that belief, the impact of an accommodation on the Coast Guard's compelling need for a healthy military force capable of fulfilling its statutory missions, and whether there are less restrictive means available to the individual and their unit to meet that compelling interest.

25. Each religious accommodation request is necessarily different because each Coast Guard member's circumstances are unique. Accordingly, each request is reviewed in light of these particularized differences.

26. The Coast Guard manages six major operational mission programs—maritime law enforcement, maritime response, maritime prevention, marine transportation system management, maritime security operations, and defense operations—and is charged with eleven statutory missions—marine safety, search and rescue, aids to navigation, living marine resources, marine environmental protection, ice operations, ports waterways, and coast security, drug interdiction, migrant interdiction, and law enforcement. Coast Guard members serve in assignments across these missions and across the globe, and they have a wide range of roles and responsibilities in these assignments. A particular member's location, occupational role, responsibilities, and duties vary. Their proximity to, and amount of time they must work with, other members of the Coast Guard, other military services, and with the public differ. Their ability to distance themselves from others and continue to perform the mission varies, as does the likelihood that they will be required to deploy on short notice to respond to an emergency. Nevertheless, all personnel must be available for unrestricted duty assignment worldwide.

27. Members aboard a cutter, for example, work in close proximity with other Coast Guard members and share berthing areas with only a few feet between their racks and hygiene facilities. Members of aircraft crews may work in smaller teams but in consistently enclosed spaces, in close proximity. Others in support roles may work in office environments where greater social distancing and other risk mitigation measures are possible to employ, whereas members serving in medical roles must have face-to-face contact with their patients. These

particularized circumstances are considered in reviewing each individual religious accommodation request.

28. The Coast Guard has a compelling interest in maintaining a healthy, effective military workforce required for mission accomplishment at the individual, unit, and organizational level, including in maintaining military readiness, unit cohesion, good order and discipline, and health and safety. To fulfill the eleven statutory missions, Coast Guard members are assigned across the United States and around globe. The Coast Guard's motto is "Semper Paratus": Always Ready. Its members perform these missions 24 hours a day, seven days a week and must be ready to deploy to respond to emergencies with little or no notice. Mandatory vaccination against COVID-19 is vital to ensuring the Coast Guard is able to achieve its statutory missions by ensuring the Coast Guard has a healthy, ready force.

29. A member initiates the process of seeking a religious accommodation by submitting a memorandum request through the member's Commanding Officer or Officer-in-Charge using an approved template found in Enclosure 2 of CI1000.15. The memorandum should describe the specific request the member is seeking, whether or not the member has previously had this or any other policy waiver request approved or denied, the religious beliefs on which the exemption request is based, how current policy prevents the member from practicing within their beliefs, and the relation to the sincerely-held belief on which the request is based. Although not required, some members have also included correspondence from clergy or other material to support their request.

30. After the request is submitted, a medical officer and a chaplain will meet individually with the requester. The medical officer must consult with the requester and provide specific information about the diseases concerned, specific vaccine information, and the potential risks for unimmunized individuals. *Id.* 12.h. The medical officer may document the counseling in a memo

that includes the officer's opinion as to whether the member has the contraindication to receipt of the COVID-19 vaccines. The medical officer consult must be noted in the member's religious accommodation request memo.

- 31. A chaplain also interviews the member using the Religious Accommodation Interview Checklist found in Enclosure 3 of CI1000.15. The chaplain's interview can be very useful to the various reviewers in understanding whether the request is actually based in a religious belief rather than a political, moral, or scientific belief. Some requests for religious accommodations may not actually stem from a religious belief, or may combine a religious belief with another rationale for departing from policy (e.g., a requester might have a religious objection to an mRNA vaccine, but not to a vaccine that uses a weakened or inactivated vaccine to produce the immune response). In assessing the sincerity of the requester, the chaplain must not base his or her opinion on the chaplain's personal religious beliefs or interpretation of what constitutes an appropriate religious or other practice, but must focus instead on the importance of the request to the requester in terms of religious beliefs or principles, given the information provided. *Id.*
- 32. The chaplain then prepares a memorandum memorializing the interview using guidance provided in Enclosure 5 of CI1000.15. A copy of this memorandum is provided to the requester. Although there is no required template for the chaplain to use, Enclosure 5 of CI1000.15 provides a detailed list of questions the memorandum should address. The topics to be addressed include a description of the exception to policy being requested, including the nature of the religious or other practice and how it conflicts with applicable policy. The memo should explain whether or not policy completely prohibits the practice and whether or not the member has previously had this or any other accommodation request approved or denied. It should describe what the requester

understands to be the underlying basis for the request and include a description of the religious beliefs on which the waiver request is based. It should also include how the requester expresses those beliefs or principles in daily life and what the requester lists as a religious preference. The chaplain will provide their professional opinion regarding the sincerity of the requester and opinion regarding the importance of the request to the requester.

33. Once these interviews are completed, the member's Commanding Officer or Officer-in-Charge reviews the request package, including any enclosures provided by the requester, and considers the religious objection of the member, the medical risk to the member and the unit, and the effect on Coast Guard readiness requirements, such as alert status, deployment potential, and availability of the member for reassignment to units requiring full medical readiness. The Commanding Officer or Officer-in-Charge is also encouraged to consult with their Servicing Legal Office. The Commanding Officer or Officer-in-Charge endorses the request either by signature with no comment or with a separate written endorsement. The endorsement may include a recommendation regarding whether or not to separate the member and may highlight any command concerns regarding staffing needs or other issues relevant to the unit. For example, a reserve unit could be scheduled to deploy in the near term which might significantly limit the unit's ability to mitigate risk by social distancing, may place the requester in an area with high community transmission, or may include country-specific vaccination requirements that preclude the member from traveling altogether.

34. The request package is then forwarded to Coast Guard Headquarters, where it is reviewed by the Office of Health Services, CG-112, and processed by the Office of Military Personnel Policy's Military Policy Development Division, CG-1331, which develops a recommended response. Multiple individuals within each office participate in the review. The request is then

forwarded to the final approval authority, the Office of Military Personnel Policy, CG-133 (or designated alternate). The final decision on the request is made by the Chief, CG-133, a senior Coast Guard officer serving in the rank of Captain (O-6), or by his or her designated alternate, and includes a legal sufficiency review by the Office of General Law, CG-LGL. The decision is based on CG-133's review of the request package in light of the Religious Freedom Restoration Act of 1993 and applicable Coast Guard policy. The decision maker considers the sincerity of the member's religious beliefs, the extent to which the vaccine requirement burdens that belief, the government's compelling interest in mission accomplishment, and whether requiring vaccination against COVID-19 is the least restrictive means of achieving this compelling interest. Ultimately, CG-133's decision is memorialized in a memo explaining the decision. A copy is provided to the requester.

35. By policy, a member whose request is denied may administratively appeal a denial to the Director of Military Personnel (CG-13). All COVID-19 religious accommodation request appeals are currently adjudicated by myself, the Deputy for Personnel Readiness.⁷ The appellate authority reviews the CG-133's denial for error, and in doing so considers the requester's appeal memorandum, the denial decision memo, endorsement, the request package reviewed by CG-133, and the executive summary prepared by legal.

36. The approval authority must review and make a decision on the accommodation request within 30 business days of the date the service member submitted an accommodation request. The Deputy for Personnel Readiness must reach a final decision on the appeal within 30 business days from the date the service member provided notice of an intent to appeal. If there a large influx of

⁷ Previously because of the large number of COVID-19 religious accommodation request appeals, I delegated the authority to act as an appellate authority to three additional individuals: RDML Miriam L. Lafferty, Assistant Commandant for Reserve, and two members of the Senior Executive Service, Mr. James Knight and Ms. Dana Tulis.

religious accommodation requests—like the historically large influx of requests related to the COVID-19 vaccination—then these timelines may not be met.

37. Service members with pending active requests for medical and religious exemptions, including appeals, are temporarily deferred from immunizations, pending outcome of their request. That means that they are not required to vaccinate unless and until they are ordered to do so following a denial of a request or appeal. The Coast Guard will take no disciplinary or administrative action against any Coast Guard member based on their unvaccinated status while the member has a pending medical exemption or religious accommodation request. Unvaccinated members, however, remain subject to disciplinary action or separation from military service for other reasons unrelated to vaccination, *e.g.*, failure to meet weight standards or a failure to go to the member's place of duty. They may also still be subject to additional measures necessary to mitigate health risks to other members and the public. These measures may include additional restrictions on official travel, liberty (i.e. off-duty hours), and leave, as well as cancellation of "A" and "C" school orders.

III. Processes after Denial of an Exemption Request

38. Members whose requests are denied are counseled by their command concerning the timeline to initiate vaccination. Upon notification of the final request denial, the standard timeline to initiate vaccination is within 10 business days of notification.

39. If an unvaccinated member's request for medical exemption and/or administrative exemption, including religious accommodation, is denied and the member still refuses to be vaccinated, the member would then be subject to possible disciplinary action or administrative separation from the Coast Guard. Before either action could take place, the Coast Guard would have to engage in specific processes set forth in either the Military Separations Manual,

COMDTINST M1000.4, or the Military Justice Manual, COMDTINST M5810.1G, and the Uniform Code of Military Justice.

40. On July 22, 2022, the Coast Guard issued supplemental guidance initiating involuntary administrative separation processing for all non-compliant Active Duty service members and processing for involuntary transfer to the Inactive Status List (ISL) for all non-compliant Reserve service members. ALCOAST 270/22. The effective date of any individual member's separation may be influenced by the needs of the Service—including, but not limited to: rate, officer specialty, and command concerns. However, non-compliant members who elect to receive an approved COVID-19 vaccine prior to their effective separation date will be removed from the involuntary separation process and restored to their prior active duty or reserve status. The characterization of discharge for any members separated for non-compliance with the vaccine mandate will be no less than General under Honorable Conditions.

41. The process required to administratively separate a Coast Guard member varies depending on a number of factors, such as the basis for separation, length of service, whether the member is a commissioned officer, chief warrant officer, or enlisted member, and type of commission. The various processes are detailed in the Coast Guard's Military Separation Manual, COMDTINST M1000.4.8

42. For example, a commissioned Regular Coast Guard officer with greater than five years of commissioned service, 9 who is not granted a waiver based on a medical or religious exemption request, and remains non-compliant with vaccination requirements, could be considered for

⁸ COMDTINST M1000.4, 1.A.14, outlines the process for separating regular Coast Guard Officers for Cause. Section 1.A.10 outlines the process for revoking a regular officer's commission in the first five years of service for cause. Section 1.B outlines the process for separating enlisted members.

⁹ If the member has less than five years of commissioned service, she could be considered for separation from service in accordance with COMDTINST M1000.4, 1.A.10; and the statutory requirement of 14 U.S.C § 2159.

separation from service in accordance with COMDTINST M1000.4, 1.A.14, and the statutory requirements of 14 U.S.C. §§ 2158 – 2164. These requirements include a review of their personnel record by the Personnel Service Center (PSC) and the convening of a determination board, which could either require the officer to show cause for retention in the Coast Guard or close the case. If the determination board decides to require the officer to show cause for retention, a board of inquiry is convened to afford a fair, impartial hearing at which the officer and their counsel have an opportunity to show that retention is warranted. The officer would be afforded the opportunity to be represented at the board of inquiry at no cost by a Coast Guard attorney, or to obtain private civilian counsel. After hearing the evidence, including any the officer might wish to present, the board of inquiry makes findings and recommends whether the officer should be retained or separated from the Coast Guard. If the board of inquiry recommends separation, the Commander of PSC convenes a board of review to review the record and documented evidence and determine whether to retain or separate the officer. If any of the three boards—the determination board, the board of inquiry, or the board of review—determines that the officer should be retained, then at that point the officer is retained and the case is closed. If the board of review recommends separating the officer, the board of review's recommendation is forwarded to the Commandant for review. The Commandant may disapprove a recommendation to discharge an officer, but may not overrule a determination to retain the officer. If the Commandant approves the boards' recommendation to discharge the officer and the officer is entitled to voluntary retirement under any provision of law, the officer is retired in the grade they would be retired as if they had requested voluntary retirement. If the officer is not entitled to retirement under any provision of law, they are honorably discharged with separation benefits under 14 U.S.C. § 2146(c) unless, under regulations promulgated by the Secretary, the condition under which the officer is discharged does

not warrant an honorable discharge.¹⁰ While the time for completing this process varies, generally this process takes at least six to nine months to complete, and can take over a year due to resolving scheduling conflicts, acting on requests for extensions of time to prepare, making transcriptions of proceedings, and other administrative concerns.

43. An unvaccinated member whose request for medical exemption or religious accommodation is denied and who refuses a lawful order to get vaccinated is also subject to discipline pursuant to the Uniform Code of Military Justice for violating Article 92, 10 U.S.C. § 892. The punishment for violating Article 92 could include dismissal from the Coast Guard, which can only be awarded at a general court-martial. R.C.M. 1003(b)(8)(A). At this time, however, no Coast Guard members have faced or are facing disciplinary action solely for a failure to obey a lawful order to get vaccinated.¹¹

44. Coast Guard policy provides Coast Guard members with the opportunity to seek medical exemptions or religious accommodations to the COVID-19 vaccination requirement. While such requests are pending, the Coast Guard will take no adverse administrative or disciplinary actions against members. For Coast Guard members who choose not to pursue an exemption, or have their requests denied, and still refuse to be vaccinated, the Coast Guard is initiating involuntary separation processing. Each Coast Guard member subject to involuntary separation will receive

¹⁰ Officers in the process of going through involuntary board action may, in accordance with article 1.A.21 of COMDTINST M1000.4, request to separate in lieu of completing the board process. If this is permitted, the officer will receive the same category of Separation Program Designator code on their Certificate of Release or Discharge from Active Duty, DD Form 214, that they would if the board process went to completion with a decision to separate.

¹¹ Prior to charges being referred to a general court-martial for trial, a preliminary hearing is conducted. At that hearing, the member may be represented by a detailed military attorney at no cost and may present evidence and cross-examine witnesses. R.C.M. 405. After the preliminary hearing, charges can be referred to a general court-martial, but only by one of a limited number of Coast Guard admirals who are general court-martial convening authorities. 10 U.S.C. § 822. At the general court-martial, the member would again have the right to be represented by their detailed military attorney, to present evidence, and to cross examine witnesses. This entire process from referral of charges to court-martial generally takes several months, or more, to complete.

all processes required to administratively separate them based on their particular circumstances, including their length of service, whether they are a commissioned officer, chief warrant officer, or enlisted member.

I hereby declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the foregoing is true and correct to the best of my knowledge and information.

Dated: October 42022

Rear Admiral U.S. Coast Guard Deputy for Personnel Readiness

Exhibit 4

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

ERIC JACKSON, ALARIC STONE, and)	
MICHAEL MARCENELLE, on behalf of)	
themselves and all others similarly situated,)	
•)	Case No. 4:22-cv-00825-P
Plaintiffs,)	
V.)	
)	
ALEJANDRO N. MAYORKAS, in his official)	
capacity as Secretary of Homeland Security,)	
LLOYD J. AUSTIN, III, in his)	
official capacity as Secretary of Defense,)	
LINDA L. FAGAN, in her official)	
capacity as Commandant of the Coast Guard, and)	
BRIAN K. PENOYER, in his official capacity)	
as Assistant Commandant for Human)	
Resources of the Coast Guard,)	
,)	
Defendants.)	

DECLARATION OF LIEUTENANT COMMANDER JOEL A. ABER

I, LIEUTENANT COMMANDER JOEL A. ABER, hereby declare and state:

1. I am a reserve commissioned officer serving on active duty in the United States Coast Guard. I have served in the Coast Guard for 18 years. I was recalled to active duty on January 1, 2022 to serve as the COVID-19 Crisis Action Team Support Cell Leader and assumed my current assignment as the COVID-19 Crisis Action Team Leader upon the retirement of CAPT Timothy Buchanan, the previous Team Leader, in June 2022. My prior Coast Guard assignments have included Shoreside Security and Tactical Action Officer at Port Security Unit 308, Integrator at Force Readiness Command, Direct Action Section Team Leader and Precision Marksman Division Chief at Maritime Security Response Team East, Deployable Team Leader and Instructor at the International Training Division of Training Center Yorktown, and Homeland Security

Liaison at Group Galveston. I am generally aware of the allegations set forth in the pleadings filed in this matter and make this declaration in my official capacity, based upon my personal knowledge and upon information that has been provided to me in the course of my official duties.

- 2. The COVID Crisis Action Team was established in March of 2020 as a cross-functional team consisting of approximately 30 work groups responsible for the rapid coordination of Coast Guard wide policy and direction in response to the SARS-COV-2 world wide pandemic. The team reports directly to the Coast Guard Deputy Commandants for Mission Support and Operations, with direct liaison authorization to Coast Guard Areas, Districts, and Field units in managing the daily Coast Guard pandemic response. The team's areas of emphasis are safety, efficiently sustaining Coast Guard operations and mission support, and directly supporting the American public.
- 3. The Coast Guard is one of our nation's military services and, in addition to defense operations, has eleven statutory missions: marine safety; search and rescue; aids to navigation; living marine resources; marine environmental protection; ice operations; ports, waterways and coastal security; drug interdiction; migrant interdiction; and other law enforcement. On an average day, the Coast Guard will, amongst other things, conduct 45 search and rescue mission saving 10 lives and over \$1.2 million in property; investigate 35 pollution incidents; screen 360 merchant vessels for potential security threats prior to arrival in U.S. ports; conduct 105 marine inspections of vessels; and investigate 14 marine casualties while facilitating the movement of \$8.7 billion worth of goods and commodities through the Nation's Maritime Transportation System. Coast Guard members serve in their local communities throughout the Continental United States, Alaska, Hawaii, and United States territories stretching from Guam to the Virgin

¹ 6 U.S.C. § 468.

² United States Coast Guard > Values Video (uscg.mil)

Islands. Coast Guard members are assigned to foreign countries ranging from China to Europe and Coast Guard cutters routinely engage in migrant and drug interdiction operations in to the Caribbean and the Eastern Pacific; in fisheries conservation boardings in the Atlantic, the Gulf of Mexico, and the Bering Sea; in support of defense operations with the Navy or allied naval forces in the Western Pacific and Indian Oceans; and icebreaking operations in the Artic and Antarctica.

- 4. To perform these missions, Coast Guard personnel consistently find themselves in close proximity to both each other and members of the public. Vessel boardings for law enforcement operations, migrant interdictions, marine inspection of commercial vessels, oil spill clean up operations, and rescue operations all routinely bring Coast Guard members into close personal contact with members of the public without the opportunity to socially distance themselves or screen them for vaccination status. Coast Guard members aboard cutters, small boats, and aircraft must work in close proximity to each other. Members aboard cutters are required to share berthing areas with just a few feet between tiered racks and to share shower and toilet facilities. Even members assigned to shore duties may be assigned to standing watch in command centers for lengthy shifts without the ability to social distance, and boat crews must sleep and eat aboard their small boat stations in order to be ready to respond to search and rescue missions. Coast Guard operations are not compatible with physical distancing, isolation, and quarantine measures that have been used to combat COVID-19.
- 5. In addition to these regular round-the-clock operations, Coast Guard members must also be ready to provide personnel for short-fuse deployments and no-notice temporary duty assignments to execute its own authorities and to assist other agencies. For example, in Fiscal Year 2021, the Coast Guard deployed 4,461 members (both active duty and reserve) in response to surge staffing operations, including Hurricane Ida, Operation Allies Welcome, the California

Pipeline oil spill, M/V *Golden Ray* capsizing, the Haitian earthquake, and Southwest Border migrant operations. That number accounts for over 10% of the Coast Guard's total military end strength. The majority of the personnel who are assigned to respond to the domestic emergencies are assigned from non-operational billets, as those members assigned to operational assets are deemed to be critical to the execution of that asset's mission. Mitigation measures short of full vaccination, like testing and social distancing, cannot be implemented during these deployments and temporary duty assignments because of the nature of the operational environment and the often austere and arduous situations in which the members operate.

6. To fulfill these emergency deployments, active duty Coast Guard members may only receive hours' notice prior to their departure for international or domestic deployments. Coast Guard reservists also may receive little advance notice. In the case of involuntary recall under 14 U.S.C. § 3713, a member of the Coast Guard Reserve is given only "a reasonable time" between notice and date of activation. The standard period is "at least two days" but that can be shorter if the Secretary determines the domestic emergency does not allow for the full two-day period.³ Because of the mission-critical need to get members onto the scene of domestic emergencies as fast as possible, the Coast Guard's surge staffing office seeks to achieve a two- to three-day turnaround time between receipt of request for surge staffing and the arrival of the member onscene. It is also not possible for the Coast Guard to allow members to remain unvaccinated until they are ordered to respond to a domestic emergency or contingency operation because three to four weeks are required between the first and second doses of the vaccine.⁴ If the Coast Guard allows temporary deferment of vaccination until notice of deployment or temporary duty

³ 14 U.S.C. § 3713(b).

⁴ https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#recommendations, last accessed August 29, 2022.

assignment, then the member will be unable to execute those orders in a timely manner. Therefore, Coast Guard members must be vaccinated in advance of any deployment notification to ensure the Coast Guard is able to fulfill its ongoing and foreseeable future responsibilities to respond to domestic emergencies and crises. No other alternative is adequate to ensure the successful and safe deployment of the Coast Guard's forces in response to our Nation's emergencies.

- 7. As of October 5, 2022, a total of 8,247 Coast Guard members have been infected with COVID-19 from a current total force of 39,758 active duty members and 6,142 reservists. Coast Guard units are often small in size such that even a small number of cases can render a unit incapable of performing its mission. As an illustrative example, Sector Houston-Galveston is part of the Eight Coast Guard District, which is responsible for most of the Gulf of Mexico coastline as well as the inland waterways of the Mississippi, Ohio, Missouri, Illinois, and Tennessee River systems. Thirty-nine separate units in District Eight were rendered Not Mission Capable (NMC) due to COVID-19 at least once, eleven units were NMC more than once. Included in this total is the Coast Guard Cutter MALLET, a 75' inland construction tender, has been rendered NMC by COVID-19 three times leaving it out of operation for a total of 33 days. MALLET is responsible for maintaining and repairing 1,328 floating and fixed Aids to Navigation and is also called upon at times to complete construction projects and occasionally salvage operations. Aids to navigation are vital to safe maritime commerce. If MALLET is not able to service its aids, those aids may be off station, not lit, or missing entirely, thereby increasing the possibility that commercial vessels may round aground and possibly result in an oil spill. Also included in this total was the cutter KANKAKEE, another 75' inland construction tender, which was NMC three times for a total of 26 days.
 - 8. By the end of October 2021, across the Coast Guard, 133 units were NMC at least

once due to COVID-19. These units ranged in size from several small Aids to Navigation Teams to the 418' National Security Cutter STRATTON, which had to end a seven week counternarcotics patrol just two weeks into a planned seven-week patrol after 11 crew members tested positive for COVID-19 despite all crew members undergoing a period of self-quarantine and passing two coronavirus tests prior to getting underway.

- 9. The worst impacts to Coast Guard readiness came in the fall of 2020, prior to the availability of vaccines. The peak impact occurred from November 9 through 19, 2020, during which time period between ten and fourteen Coast Guard units were NMC every day. Starting in March 2021, as Coast Guard members started to receive their second vaccination shots, readiness improved dramatically. While the numbers of NMC units rose during the COVID-19 Delta variant wave, they peaked at August 4, 2021, at seven NMC units. As the number of Coast Guard members who are fully vaccinated has risen, availability improved. During the months of September and October 2021, just ten Coast Guard units were in a NMC or partially mission capable (PMC) status. Of those ten units, only one had a fully vaccinated crew. This status largely continued for two months through December 25, 2021. On most days no NMC units were reported and on no day was more than one Coast Guard unit in a NMC status.
- 10. At the start of this year, the Omicron variant of the COVID-19 virus became the predominant variant in the United States and the number of Americans infected with COVID-19 increased dramatically. During the peak in early January 2022, the Center for Disease Control and Preventing ("CDC") reported 1,263,230 new COVID-19 cases on January 10, 2022, more than four times higher than the previous highest daily total.⁵ The Coast Guard also felt the impact of the Omicron variant experiencing its peak operational impact the following day, with thirteen

⁵ See CDC, COVID Data Tracker (last accessed August 29, 2022), https://covid.cdc.gov/covid-data-tracker/#trends_dailycases_select_00.

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Coast Guard units NMC. The impact, however, quickly dropped and by the end of the month just

one unit was NMC. On February 14, 2022, zero Coast Guard units were NMC and remained at

zero for months. As a result, the Coast Guard no longer finds it necessary to track this metric.

While the impacts to operational readiness at the peak of the Omicron variant were significant,

they are not as severe as the previous high from November 2020 (seven to fourteen NMC units per

day throughout the month). The November 2020 high occurred before vaccines were available,

but also at a time when the nationwide total of new daily cases nationwide was less than a quarter

the number of cases experienced during the Omicron variant peak. Based on this prior experience,

the Coast Guard would have expected a much higher number of NMC units if our service members

remained unvaccinated. This is a clear indication that vaccination had a positive impact on Coast

Guard mission readiness.

11. Individual readiness is the key building block for unit readiness. Vaccination

remains the best method for an individual Coast Guard member to protect himself and his

shipmates from severe disease, hospitalization, and death.

I hereby declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the foregoing

is true and correct to the best of my knowledge and information.

Dated: October 6, 2022

ABER.JOEL.ALL ABER.JOELALLEN.1153844824 EN.1153844824 Date: 2022.10.06 15:40:00

JOEL A. ABER Lieutenant Commander

U.S. Coast Guard

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Exhibit 5

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

ERIC JACKSON, ALARIC STONE, and)	
MICHAEL MARCENELLE, on behalf of)	
themselves and all others similarly situated,)	
•)	Case No. 4:22-cv-00825-P
Plaintiffs,)	
V.)	
)	
ALEJANDRO N. MAYORKAS, in his official)	
capacity as Secretary of Homeland Security,)	
LLOYD J. AUSTIN, III, in his)	
official capacity as Secretary of Defense,)	
LINDA L. FAGAN, in her official)	
capacity as Commandant of the Coast Guard, and)	
BRIAN K. PENOYER, in his official capacity)	
as Assistant Commandant for Human)	
Resources of the Coast Guard,)	
)	
Defendants.)	

DECLARATION OF COMMANDER BROOKE GRANT

- I, Commander Brooke Grant, hereby declare and state:
- I am a commissioned officer serving on active duty in the United States Coast Guard. I have served on active duty in the Coast Guard for over 20 years and am currently serving as Chief, Military Personnel Policy Development Division (CG-1331). I have served in this position since August 2021. My prior assignments include Logistics Department Head, United States Coast Guard Sector Key West; Deputy, Office of Legal Policy and Program Development; and Staff Attorney, United States Seventh Coast Guard District Legal Office. I am generally aware of the allegations set forth in the pleadings filed in this matter and make this declaration in my official capacity, based upon my personal knowledge and upon information that has been provided to me in the course of my official duties. CG-1331 is the Coast Guard Headquarters office that originally receives requests for religious accommodation from the COVID-19 vaccination

requirement.

- 2. Exhibit 1, attached to this declaration, provides updated data with respect to the COVID-19 vaccination requirement. However, certain data elements are either not available or require further explanation.
- 3. Requests for religious accommodation from the COVID-19 vaccination requirement in the Coast Guard are centrally managed, with the Office of Military Personnel Policy, CG-133, serving as the final approval authority. Religious accommodation requests are not tracked until they reach Coast Guard Headquarters. Accordingly, the column labeled "Total Initial Requests" reflects only the number of religious accommodation requests that have been received at Headquarters. Most requests for a religious accommodation from the COVID-19 vaccination requirement have been adjudicated.
- 4. In March 2022, the Coast Guard granted an administrative exemption to the vaccination requirement for all members with an approved separation or retirement date no later than October 1, 2022. The Coast Guard did not act on any pending religious accommodation requests or appeals that were submitted by members who qualified for this administrative exemption.
- 5. Permanent medical exemptions from vaccine requirements are also centrally managed at Coast Guard Headquarters through the Office of Occupational Medicine, CG-112. CG-112 does not actively track the number of applications for permanent medical exemptions that have been submitted or denied. All permanent medical exemptions granted thus far are based on a documented severe allergic reaction to a COVID-19 vaccine or a component of the vaccine.
- 6. Temporary medical exemptions are processed by medical officers in the field. The Coast Guard does not maintain a database from which it can determine a complete and accurate account of all temporary medical exemptions that have been granted. In addition, because the

temporary exemptions expire and are based on medical conditions that could arise during a

reporting period (e.g., a member may be granted a medical exemption if he or she is infected with

COVID-19 and therefore ineligible to be vaccinated for the duration of the infection and for a

period afterwards), changes in the total number of temporary medical exemptions from one

reporting period to another would not reflect the total number of temporary medical exemptions

that have been granted. For example, during any given period, two temporary medical exemptions

might expire and two new temporary medical exemptions might be granted, but the total number

of temporary medical exemptions would remain the same.

7. The Coast Guard has not taken any action to Courts-Martial members that have

refused an order to become vaccinated. The Coast Guard has initiated administrative separations

for enlisted members and board action for officers who have not complied with COVID-19

vaccination requirements. Administrative separation packages for enlisted members are prepared

by each member's command and continue to be submitted to the Personnel Service Center at Coast

Guard Headquarters. Of the administrative separations that have been completed, all but one

member received a discharge with a characterization of honorable. The member who received a

characterization of General under honorable conditions had a documented record of significant

misconduct apart from the failure to be vaccinated.

8. I hereby declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the

foregoing is true and correct to the best of my knowledge and information.

Dated: October 7, 2022

Brooke Grant Digitally signed by Brooke Grant Date: 2022.10.07 12:18:57 -04'00'

BROOKE GRANT

Commander

U.S. Coast Guard

Exhibit 1 to Declaration of CDR Grant

U.S. Coast Guard COVID-19 Vaccination Requirement Data

Current as of 16 September 2022

(1) Number of religious exemption from COVID-19 vaccination:

# Initial Requests Under Review	# Initial Request Approved	# Initial Requests Denied	Total Initial Requests
2	5	12381	1346

			Fully Resolv	ed Requests
# Appeals Under Review	# Appeals Denied	# Appeals Approved	Aggregate # of Approved Requests	Aggregate # of Denied Requests
5	885 ²	7	12	1189

(2) Number of medical-exemption requests from COVID-19 vaccination:

Temporary Medical Exemption Requests	Permanent Medical Exemptions Denied	Permanent Medical Exemptions Granted	Total Permanent Medical Exemption
	Denied		Requests
Unknown	Unknown	9	Unknown ³

(3) Number of courts-martial and separation proceedings pending or concluded against a service member whose request for a religious exemption was denied after appeal:

Courts-Martial		Administrative S	eparation (ADSEP)
Pending	Concluded	ADSEP Initiated	ADSEP Completed
0	N/A	>1904	136

¹ This does not include members who submitted a religious accommodation request but then took advantage of the administrative exemption.

² This does not include members who submitted a religious accommodation appeal but then took advantage of the administrative exemption.

³ The Coast Guard is not actively tracking requests and continues to process permanent medical exemption requests when received.

⁴ Administrative separation packages are not tracked until they are received at Coast Guard Headquarters. Units continue to prepare and submit packages for unvaccinated members.

Exhibit 6

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

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)	
)	
)	Case No.
)	
)	
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)	
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DECLARATION OF COMMANDER MICHAEL C. THOMAS

I, Michael C. Thomas, hereby state and declare as follows:

1. I am a Commander in the United States Coast Guard currently assigned as Executive Officer, United States Coast Guard Cutter (USCGC) JAMES (WMSL-754). I have been in this position since June 2021. As of the date of this declaration, I am serving as Acting, Commanding Officer of USCGC JAMES. USCGC JAMES is one of the Coast Guard's premiere National Security Cutters (NSC), the fifth NSC of the Legend-class cutters built for the United States Coast Guard. The NSC are minimally crewed ships with approximately 125 personnel, built for 60+ day deployments in support of Coast Guard missions to include maritime homeland security,

law enforcement, and national security. These ships were built to replace the Coast Guard's aging Hamilton class cutters after their 40 years of service. The NSC was designed with a maximum speed of 28 knots and a range of 12,000 nautical miles. The ship features advanced command, control, communication, computers, intelligence, surveillance, and reconnaissance equipment, as well as aviation support facilities and stern boat launch capability. USCGC JAMES was recently engaged in Counter Transnational Organized Crime (CTOC) deployment within the Eastern Pacific Ocean engaging in disruption and confiscation of illegal narcotics movements from Central and South America bound for the United States. In 2021 USCGC JAMES alone interdicted over 30,000 kilograms of cocaine and 15,000 pounds of marijuana in support of Operation Martillo.

2. I am generally aware of the allegations set forth in the pleadings filed in this matter. I make this declaration in my official capacity as Acting, Commanding Officer, USCGC JAMES and based upon my personal knowledge and upon information that has been provided to me in the course of my official duties.

LIEUTENANT JUNIOR GRADE ALARIC STONE

3. LTJG Alaric Stone is an active duty commissioned officer in the United States Coast Guard, previously assigned on board USCGC JAMES as a member of the Operations Department. LTJG Stone transferred from USCGC JAMES on 20 June 2022 and reported to Fifth District Intelligence Branch (DRI), located in Portsmouth, Virginia, on 01 July 2022. LTJG Stone was a fully qualified junior officer on board USCGC JAMES, to include Basic and Advanced Damage Control as well as Inport and Underway Officer of the Deck (OOD), responsible for shiphandling and safety of the crew and cutter.

- 4. LTJG Stone participated in four separate NSC deployments while attached to USCGC JAMES. Each deployment consisted of approximately 90 days at sea with various port calls in foreign countries for logistics and crew rest. His work on the ship put him in close contact with over 126 Coast Guard service members in close quarters aboard the ship with the potential for close contact with foreign military and civilian members during port calls and other international engagements. Telework and social distancing was not an option for his position while attached to USCGC JAMES. LTJG Stone was required to deploy in order to meet the mission needs of the ship and the Coast Guard. At the height of the COVID-19 pandemic while underway and in homeport, he was required to wear an N95 mask at times in order to protect his own health and the ship's crew.
- 5. A COVID-19 positive member puts the unit at risk for spreading the disease to other crew members and the public. The crewmembers of USCGC JAMES must remain world-wide deployable in order to accomplish the mission, and when shipmates test positive, they may not be deployed or are required to be quarantined while underway, resulting in reduced mission capability, which ultimately hinders the ability of the unit to serve the public.
- 6. LTJG Stone was counseled on 09 September 2021, regarding the requirements to be vaccinated against COVID-19 and indicated that he intended to seek a medical or religious exemption. On 22 September 0 2021, LTJG Stone forwarded his request to Coast Guard Headquarters (CG-133), through myself as the Executive Officer (XO) with an endorsement from the Commanding Officer (CO), CAPT Todd Vance, stating that CGC JAMES was unable to support LTJG Stone's request noting an inability to maintain mission readiness for USCGC JAMES and protect crew members and their families during the global pandemic. The religious accommodation request required a meeting with a medical officer and chaplain.

- 7. I am aware that in his request for religious accommodation LTJG Stone understood the CO to say that his religious beliefs and those of the two other unvaccinated crew members seeking a religious accommodation "did not matter" to him. I believe they misinterpreted his remarks. CAPT Vance was adamant that the nature of their religious beliefs did not play a role in his endorsement of their request. His endorsement was based on his belief that vaccination was necessary to the ship meeting operational mission requirements and keeping the crew/families healthy and safe. In the Coast Guard's religious accommodation process, the chaplain meeting and memorandum provides the information about the member's religious beliefs to the authority deciding to grant or deny the request. Because the requested accommodation concerned a mandatory vaccination, CAPT Vance did not have the authority to grant or deny the request.
- 8. LTJG Stone's request for religious exemption was denied. LTJG Stone had already begun his PCS transfer to Fifth District Intelligence Branch when he was notified of the denial. I provided an email to LTJG Stone and informed his new command. To my knowledge, LTJG Stone's new command then issued the required CG-3307documentation ordering him to receive the vaccination and documenting his refusal to vaccinate and violation of Articles 90 and Article 92(2) of the Uniform Code of Military Justice (UCMJ).
- 9. The Coast Guard has centrally implemented certain administrative risk mitigation measures to maximize mission readiness and to minimize the safety risks presented to, and resulting from, unvaccinated members. One of those measures is to require that leave requests from unvaccinated members involving travel more than 50 miles from the member's worksite or home must be approved by the first Captain (O-6) in the member's chain of command. I am not

aware of any leave request from LTJG Stone that had been denied because of his vaccination status.

- 10. LTJG Stone would need to be vaccinated to fully perform his duties if he were still a crewmember on board USCGC JAMES. LTJG Stone would not be able to telework or socially distance at all times and still accomplish his job requirements, which required his physical presence on board USCGC JAMES, or at other units as the need arises; and which require inperson interaction with Coast Guard and other community partners throughout the Atlantic Area. I understand that at his current assignment in District Five he works in a Sensitive Compartment Information Facility (SCIF) to enable him to work with classified systems and classified information. He cannot work on classified systems or with classified information while teleworking.
- 11. Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed this 6th day of October 2022.

Michael C. Thomas

Commander, U.S. Coast Guard Acting, Commanding Officer, USCGC JAMES (WMSL-754)

Exhibit 7

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

ERIC JACKSON, ALARIC STONE, and)
MICHAEL MARCENELLE, on behalf of)
themselves and all others similarly situated,)
•) Case No. 4:22-cv-00825-l
Plaintiffs,)
v.)
)
ALEJANDRO N. MAYORKAS, in his official)
capacity as Secretary of Homeland Security,)
LLOYD J. AUSTIN, III, in his)
official capacity as Secretary of Defense,)
LINDA L. FAGAN, in her official)
capacity as Commandant of the Coast Guard, and)
BRIAN K. PENOYER, in his official capacity)
as Assistant Commandant for Human)
Resources of the Coast Guard,)
)
Defendants.)

DECLARATION OF CAPTAIN RYAN D. MANNING

I, Ryan D. Manning, hereby state and declare as follows:

EDIC LACECON ALADIC CTONE - ... 1

1. I am a Captain in the United States Coast Guard currently assigned as Commander, Sector Los Angeles – Long Beach. I have been in this position since June 2022. As of the date of this declaration, I am serving as Sector Commander. As Sector Commander, I serve as Captain of the Port, Officer-in-Charge of Marine Inspection, Federal Maritime Security Coordinator, and Federal On Scene Coordinator. In that capacity, I coordinate maritime safety and security, environmental protection, search and rescue, waterways management, and contingency planning operations for the navigable waterways for 350 miles of shoreline from the northern boundary at Cambria inland to the Nevada state line to the southern boundary at San Clemente inland to Arizona and cover over 64,000 square miles of ocean. This area of responsibility encompasses the Diablo Canyon Nuclear Power Plant in San Luis Obispo County, the Port of Hueneme

(which includes Naval Base Ventura), the Los Angeles-Long Beach port complex and Seal Beach Naval Weapons Station. To accomplish these missions, Sector Los Angeles-Long Beach has a workforce of approximately 459 active duty Coast Guard members and civilians. CGC BENJAMIN BOTTOMS is under my command as Sector Commander.

2. I am generally aware of the allegations set forth in the pleadings filed in this matter. I make this declaration in my official capacity as Commander, Los Angeles-Long Beach and based upon my personal knowledge and upon information that has been provided to me in the course of my official duties.

First Class Petty Officer Eric Jackson

3. Upon submitting the accommodation request, BM1 Eric Jackson was a Boatswains mate (BM) in the United States Coast Guard, and was assigned to the USCGC BENJAMIN BOTTOMS (WPC 1132) in San Pedro, CA. However, BM1 Jackson is currently assigned to U.S. Coast Guard Station South Padre Island, South Padre Island, TX. My declaration will speak to life aboard the Fast Response Cutter BENJAMIN BOTTOMS, and the ability of the CGC BENJAMIN BOTTOMS to accommodate the proposed COVID-19 mitigation requests. Further, I have included a timeline of BM1 Jackson's request for an exemption from the COVID-19 vaccination requirements in this declaration. I have been informed that while BM1 Jackson continues to decline to get vaccinated against COVID-19, his current command has requested a delay in any discharge proceedings of twenty-four months for operational reasons. That request is being routed through his chain of command to the Coast Guard Personnel Services Command for action.

Chronology of BM1 Jackson's Religious Accommodation Request

- 4. On or about September 9, 2021, LCDR David J. Zwirblis, Commanding Officer of the CGC BENJAMIN BOTTOMS, counseled BM1 Jackson regarding the requirement to get vaccinated against COVID-19. BM1 Jackson indicated that he intended to seek a medical or religious exemption from this requirement.
- 5. On or about November 7, 2021, BM1 Jackson submitted a request for religious accommodation to the Office of Military Personnel Policy, CG-133, which the command of the CGC BENJAMIN BOTTOMS processed. This included meeting with a medical officer and chaplain. On or about November 18, 2021, CGC BENJAMIN BOTTOMS forwarded this request to Coast Guard Headquarters.
- 6. On or about December 14, 2021, his request for a religious exemption was denied. On or about December 16, 2021, BM1 Jackson was notified of this denial. Following receipt of the denial, BM1 Jackson submitted his appeal of the decision on or about December 27, 2021.
- 7. On or about May 5, 2022, BM1 Jackson received notification that his appeal had been denied.
- 8. On or about May 11, 2022, BM1 Jackson received a written order, directing him to get vaccinated against COVID-19. The order required BM1 Jackson to report to the Base Los Angeles-Long Beach Clinic to receive the first dose of the vaccine. On or about May 16, 2022, BM1 Jackson acknowledged receipt of the order.
- 9. On or about May 24, 2022, BM1 Jackson reported, as ordered, to the clinic, but he declined to get vaccinated.
- 10. On or about June 30, 2022, BM1 Jackson was informed via CG-3307 (P&D-41D) that he is in violation of Article 90 and Article 92(2) of the Uniform Code of Military Justice for failing

to comply with the vaccination requirement. On July 1, 2022, BM1 Jackson acknowledged receipt of this notification.

11. As of the date of this declaration, I am not aware of BM1 Jackson having been vaccinated for COVID-19.

FRC's Ability to Accommodate Proposed COVID-19 Mitigation Measures

- 12. Coast Guard Doctrine within *Coast Guard Publication 1*, states that, "the true value of the Coast Guard to the Nation is not in its ability to perform any single mission, but in its versatile, highly adaptive, multi-mission character." The Sentinel-class fast response cutter (FRC) and the people assigned to her exemplify this sentiment. The FRC is 154 feet in length, performs extended multiday patrols, and features shared berthing accommodations, a shared messing space, and close quarters work spaces. The FRCs are used for a variety of missions including search and rescue, counter drug, migrant interdiction, fisheries regulations enforcement, and homeland security where there is frequent interaction with commercial and recreational mariners, detainees, and foreign and domestic port visits.
- 13. Further, while at-sea, there is limited access to advanced medical care. If a member becomes infected with COVID-19 at sea, the cutter would need to either medivac the member off the cutter or return to port. Either one of these options would be highly disruptive to the operations of the cutter and would leave the cutter short-handed for a period of time.
- 14. BM1 Jackson proposed the following COVID-19 mitigation measures in his request for a religious accommodation request:
 - a. Follow CDC guidelines.
 - b. Wear a mask indoor public spaces.
 - c. Social distancing by staying six feet away from others.
 - d. Avoid crowds in poorly ventilated spaces.

- e. Wash his hands often.
- f. Carry 60 percent alcohol hand sanitizer.
- g. Clean and disinfect his work areas before and after use.
- h. Weekly COVID testing.
- i. Monitor his health daily for possible exposure to COVID.
- 15. The COVID-19 mitigation measures outlined in BM1 Jackson's accommodation request are not feasible, effective, or logistically viable while onboard an FRC. BM1 Jackson served as a small-boat coxswain, Boarding Officer and Deck Watch Officer. All of these are critical positions aboard the FRC where he was routinely in close proximity and in enclosed spaces with other crewmembers. This proximity made it impossible to follow CDC Guidelines, social distance, or avoid crowded spaces aboard the FRC. Due to the billet structure and absence of backup crewmembers for his positions, quarantine, isolation, and telework are not options. This makes it challenging to mitigate the spread of COVID-19 aboard the FRC at sea. Further, the working quarters onboard the Coast Guard Cutter are located in common, shared spaces, requiring daily physical presence and close interaction with crew members. Wearing a mask, washing hands, using hand sanitizer, weekly COVID-19 testing, and monitoring health daily are inadequate, with respect to time and space, to mitigate the spread of COVID-19 in close quarters situations aboard the FRC. Moreover, sanitizing the working quarters before and after use is also not feasible because, as discussed above, the working quarters are located in common, shared spaces, requiring daily physical presence and close interaction with crew members. This makes sanitization ineffective and not feasible.
- 16. The Coast Guard's mission is to ensure the safety, security, and stewardship of the Nation's waters and is renowned throughout the world for saving lives. In order to accomplish this, BM1 Jackson's position onboard the FRC necessitates frequent interaction with recreational

and commercial mariners, detainees, and members of the public during foreign and domestic port calls in an official and unofficial capacity. The inability to practice social distancing and ineffectiveness of other preventative safety measures poses a substantial risk to BM1 Jackson, his crewmembers, and the public who interact with him during the course of normal missions and operations. Moreover, a member having to wear a protective face covering during these public interactions could give the impression that the member is sick or that the member does not trust the cleanliness of the people the member is interfacing with. This could lead to increased discomfort or distrust from the public. A COVID-19 outbreak onboard a FRC will decrease the readiness of the unit, adversely impact the ability to conduct Coast Guard missions, and place the public at risk, which is contrary to our character as a service.

17. Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed and electronically signed this <u>07</u> th day of October 2022.

Ryan D. Manning

Captain, U.S. Coast Guard

Commander,

RAMA

Sector Los Angeles-Long Beach

Exhibit 8

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

ERIC JACKSON, ALARIC STONE, and)
MICHAEL MARCENELLE, on behalf of)
themselves and all others similarly situated,)
·) Case No. 4:22-cv-00825-P
Plaintiffs,)
v.)
)
ALEJANDRO N. MAYORKAS, in his official)
capacity as Secretary of Homeland Security,)
LLOYD J. AUSTIN, III, in his)
official capacity as Secretary of Defense,)
LINDA L. FAGAN, in her official)
capacity as Commandant of the Coast Guard, and)
BRIAN K. PENOYER, in his official capacity)
as Assistant Commandant for Human)
Resources of the Coast Guard,)
)
Defendants.)

DECLARATION OF CAPTAIN JOHN D. COLE

I, John D. Cole, hereby state and declare as follows:

- 1. I am a Captain in the United States Coast Guard currently assigned as Commander, Sector Charleston. I have been in this position since May 2020. As Sector Commander, I serve in official duties as described in Title 33 Code of Federal Regulations § 3.01-1(d)(1). To accomplish these missions, Sector Charleston has a workforce of approximately 360 active duty Coast Guard members and civilians.
- 2. I am generally aware of the allegations set forth in the pleadings filed in this matter. I make this declaration in my official capacity as Commander, Sector Charleston and based upon my general knowledge and upon information that has been provided to me in the course of my official duties.

Lieutenant Junior Grade (LTJG) Michael Marcenelle

- 3. LTJG Marcenelle was assigned to Sector Charleston from his graduation from Officer Candidate School and departed during the summer of Assignment Year 2022. Assigned to the Response Department as a duty officer, LTJG Marcenelle was assigned a wide range of responsibilities including serving as a qualified Law Enforcement Boarding Officer for field operations, administrative tasks, duty watchstander responsibilities in the multi-mission command center, and was the Coast Guard Auxiliary Liaison Officer. All of his duties, including the administrative tasks, required regular coordination with the public, port partners, other government agencies, and other Coast Guard personnel and Auxiliarists. The majority of his work centered on management of, and employment with, the Sector Boarding Team as they conducted security searches of arriving commercial vessels. The team, which requires a minimum of six qualified members, clears an arriving vessel during a multi-hour evolution prior to it entering into port to conduct commerce. This mission is vital to the safety, security, and prosperity of the Port of Charleston, and there are limited personnel capable of conducting these types of operations. Therefore, throughout the majority of 2020 and 2021 extra precautions were taken to limit team members' potential to COVID-19 exposure and reduce the chance of transmission between team members in order to remain resilient and fully operational.
- 4. Response Department activities were conducted in numerous locations including the Sector Command Center, where a four-person 24-hour live watch was maintained to direct emergent operations; the SeaHawk Charleston spaces, where the Sector Boarding Team was located and where interaction occurred with numerous federal, state, and local partners; and the Response Department space, an open, cubical set-up where similarly tasked officers conducted business. When conducting operational missions, LTJG Marcenelle was often in confined spaces such as a small boat or a van prior to embarking the target vessel.

- 5. Despite best efforts to wear protective equipment and maintain social distancing, the nature of duties performed in the Sector Command Center and with the Sector Boarding Team made transmission of any sickness to fellow members likely. On multiple occasions the Sector Command Center and Sector Boarding Team had to isolate after prolonged proximity to infected members, placing our ability to maintain operational readiness in jeopardy.
- 6. As an Operations Ashore Response Officer, all of the duties assigned to LTJG

 Marcenelle were foundational to his professional development and required for career

 progression. Additionally, each qualification requires a significant training investment and many
 duties are not easily transferred to other personnel.
- 7. Like all Coast Guard members, in addition to accomplishing his primarily assigned duties, LTJG Marcenelle must remain medically ready to deploy in the event he is needed for surge operations and for future Coast Guard permanent duty assignments. The COVID-19 vaccine is necessary to be fully medically ready for deployment, to shield fellow service members, and to protect the public that we are charged with safeguarding.
- 8. LTJG Marcenelle was counseled on September 09, 2021, via CG-3307, Performance & Discipline (P&D 41-A) regarding the requirement to get vaccinated against COVID-19. He indicated that he intended to seek a medical exemption or religious accommodation.
- 9. LTJG Marcenelle submitted a request for religious accommodation to the Sector Charleston command on September 13, 2021. This included the requirement to meet with a medical officer and chaplain, which was reviewed and endorsed on October 13, 2021. On October 19, 2021, I forwarded this request to Coast Guard District 7 (D7) command staff, with an endorsement stating that I was unable to support his request. The religious accommodation

request was then forwarded to Coast Guard Headquarters (CG-133) by the D7 staff after

receiving D7's concurrence.

10. The request for religious exemption was denied on May 16, 2022. Following the denial,

LTJG Marcenelle received a written order on or about May 27, 2022, directing him to get

vaccinated against COVID-19. The order required LTJG Marcenelle to report receipt of the

vaccine to Base Charleston Medical by June 03, 2022. LTJG Marcenelle did not receive a

vaccination.

11. On May 31, 2022, LTJG Marcenelle was informed via 3307 (P&D-41D) that he was in

violation of Article 90 and Article 92(2) of the Uniform Code of Military Justice. LTJG

Marcenelle departed Sector Charleston, due to Permanent Change of Station orders, on June 01,

2022, requiring issuance of CG-3307 (P&D 41D) prior to his departure.

12. As of June 1, 2022, LTJG Marcenelle's depart date from Sector Charleston, he had not

been vaccinated for COVID-19. As of this date, no adverse actions were issued for disobeying

the vaccination order. LTJG Marcenelle departed Sector Charleston for Training Center

Yorktown, Virginia with a report date of June 16, 2022. I understand that he currently serves as

an instructor at the International Maritime Officers Course which requires in person interaction

with the students including in the classroom which precludes routine teleworking.

13. Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true

and correct. Executed this 7th day of October 2022.

COLE.JOHN.D.10 Digitally signed by 22942383

COLEJOHN.D.1022942383 Date: 2022.10.07 13:37:58 -04'00'

John D. Cole

Captain, U.S. Coast Guard

Commander Sector Charleston

Exhibit 9

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                         UNITED STATES DISTRICT COURT
                        EASTERN DISTRICT OF CALIFORNIA
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                                    --000--
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                                       Docket No. 22-CV-288
      JONATHAN DUNN,
                                       Sacramento, California
                                       February 22, 2022
 4
                      Plaintiff.
                                       1:32 p.m.
 5
                 ٧.
      LLOYD J. AUSTIN, III, ET AL.,) Re: Preliminary injunction
 6
                     Defendants.
 7
 8
                          TRANSCRIPT OF PROCEEDINGS
                    BEFORE THE HONORABLE JOHN A. MENDEZ
 9
                         UNITED STATES DISTRICT JUDGE
10
      APPEARANCES (via Zoom):
11
      For the Plaintiff:
                                LAW OFFICE OF THOMAS MOLLOY, JR., by
                                MR. THOMAS MURPHY MOLLOY
12
                                1125 Wedgewood Drive
13
                                Woodway, TX 76702
      For the Defendant:
                                U.S. DEPARTMENT OF JUSTICE by
14
                                ASSISTANT U.S. ATTORNEY
                                MS. COURTNEY DANIELLE ENLOW
15
                                Assistant U.S. Attorney
16
                                1100 L Street, NW
                                Washington, DC 20530
17
18
                        JENNIFER COULTHARD, RMR, CRR
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                                 (530)537-9312
21
      Proceedings reported via mechanical steno - transcript produced
      via computer-aided transcription
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that you want me to add?

MR. MOLLOY: Yes, Your Honor. I would just like to clarify if Lt. Col. Dunn misses that October 2022 promotion board, it is possible that in a future board he could be promoted, but all of that time of missing squadron command and missing military opportunities, that's gone forever. He is behind forever from that now.

THE COURT: Okay. Thank you for that.

Ms. Enlow, anything further?

MS. ENLOW: No, Your Honor. Thank you.

THE COURT: Okay. Give me a few minutes and then we'll come back out and discuss the Court's decision on this motion. Thank you so much for responding to my questions.

(Recess at 2:44 p.m. to 2:57 p.m.)

THE COURT: Okay. Back on the record. If you freeze up again, it's on our end, so we'll let you know. Wave your hands or something and let me know if you cannot hear me.

Okay. As I indicated, I am prepared to issue a ruling on this motion today. I know that, as I said, the parties would appreciate a ruling. I know the plaintiff would appreciate a ruling, given all that's going on, on a daily basis. Again, I wish I could issue a -- and have the time and the lack of 1,000 cases to issue a more comprehensive written ruling, but the transcript is going to have to serve as the Court's ruling.

As with all motions for preliminary injunction, you start with the legal principle that preliminary injunctions are extraordinary remedies and that courts should only issue injunctive relief if, in fact, the four elements of injunctive relief, likelihood of success on the merits, irreparable harm, balance of equities and the injunction is in the public interest have been demonstrated.

This issue, the issues raised by this lawsuit, place burdens on the government to prove to the Court, in particular as we discussed in this case that the policy in this case, the requirement of vaccinating or taking a COVID-19 vaccination is in furtherance of a compelling governmental interest and, in fact, that the government is employing the least restrictive means of furthering that compelling governmental interest.

In terms of -- and focusing just -- there are two claims here upon which the plaintiff is basing his motion, his claim under the Religious Freedom Restoration Act and then his claim -- his free exercise claim under the First Amendment.

And the Court will take up both of those claims as to whether there's a basis for injunctive relief.

In terms of whether this policy is in furtherance of a compelling governmental interest, is there a likelihood of success on the merits that the Court would find that the policy is not in furtherance of a compelling governmental interest?

The evidence and the arguments at this point do convince the

Court that this policy is, in fact, in furtherance of a compelling governmental interest.

As courts have said over and over again, and this Court takes to heart, the Court must give great deference to the professional judgment of military authorities concerning the relative importance of a particular military interest.

The government -- I'm sorry. The military has argued in this case that the mandatory vaccination policy against COVID-19 is necessary to protect the force and defend the American people, that it's necessary to ensure military readiness and it's necessary to ensure the health and safety of airmen and prevent the spread of infectious disease.

This comes down to me, to this Court, in terms of what Ms. Enlow raised, as to what is an acceptable level of risk.

What level of risk is appropriate is the way that Ms. Enlow phrased it and argued it.

And, again, in this Court's view, the acceptable level of risk is a military decision that deserves great deference. And given that deference in these circumstances, it's clear to me that just on that issue of whether there is a compelling governmental interest that's been demonstrated here, that that issue comes out in favor of the military.

The plaintiff is not medically ready to deploy 100 percent, as we discussed. There are still -- even though things change from day-to-day and month to month, I can only

take this case as we sit here today. He's not medically ready to deploy to certain areas of the world where he might be required to deploy.

And it does come down, as I said, to what level of risk is appropriate. If the military can eliminate almost all risk through this policy, then there is a compelling governmental interest. And if it's going to impact, as the government has argued or possibly impact -- I don't think it's speculation that it is a possibility that this could impact both military readiness and the need to adequately deploy in a fashion that the military wants deployment to occur, that the policy is necessary.

The tougher issue is, is this the least restrictive means of furthering this compelling governmental interest?

The government argues that the practice of vaccination and ordering the COVID-19 vaccination for all members of the Air Force is, in fact, the least restrictive means in fully accomplishing what the Court has found to be a compelling governmental interest.

There were, as we discussed, at least four reasons raised by the plaintiff as to why requiring the plaintiff to be vaccinated, why it is not, in fact, the least restrictive means of furthering the government's compelling governmental interest.

The government fails to satisfy this test when there

are, in fact, other alternatives of achieving its goal without imposing a substantial burden on the plaintiff's exercise of religion.

Here, again, the Court finds that at this stage of the proceedings, obviously the case has only been in front of the Court for a week and there is a lot more evidence that would be presented over time, but as we sit here today, the Court does find that the government has met its standard of showing why the proposed alternatives are not viable options.

First, although it was briefed, it really wasn't pursued, the idea that teleworking might be a least restrictive alternative. I think both sides agree that that's not an issue that the Court needs to take up or is really being pursued. You obviously cannot telework when you're deployed.

The second is the closer issue, the tougher issue in these cases. And I wanted to also mention, as the briefs do mention, we're operating in these cases right now in an area of, in effect, first impression.

While the parties have done an excellent job of giving the Court decisions issued by district court judges from around the country facing similar issues, almost identical issues to this Court, there's no Ninth Circuit precedent, there's no Supreme Court precedent in which this statute has been applied in a military context.

Obviously these cases will be appealed and we'll start

getting some guidance, but we're operating, as I've done in many cases over the past few years, in an area where there's no case on point, there's no precedent on point. And, again, you need to look simply at instructive cases in other areas, but none of these cases are binding on this Court.

So the issue is whether the natural immunity argument raised by the plaintiff is a sufficient alternative, is a least restrictive alternative that the Air Force should follow here. And the argument that was raised is that right now there is no scientific consensus and it's not well established in the face of that uncertainty. It's not well established in terms of the data concerning natural immunity and, in the face of that uncertainty, that the Court should not and cannot accept that and find that that is, in fact, the least restrictive means of furthering the compelling government interest here.

It was several Supreme Court judges that said that judges aren't scientists. This issue involves a lot of science. I appreciate the affidavits, but affidavits aren't subject to cross-examination, they aren't subject to full-blown hearings. And while they're helpful --

I lost Mr. Molloy. Okay.

-- they don't replace full-blown hearings or a full-blown explanation of issues like this.

And absent that, I am, like many judges, reluctant to make a scientific determination. And I do agree with the

government that on this issue there is a lack of consensus, and it's not well established that a natural immunity is effective, more effective or as effective as the vaccine.

And given that uncertainty, the Air Force here has determined that the best way to minimize risk is to require vaccination. Again, there are host countries that require vaccination and given the need for the military to be able to deploy the plaintiff on short notice to any location, the natural immunity alternative isn't feasible.

The plaintiff raises another argument that routine testing would be another least restrictive means of furthering a compelling government interest. The Court finds, however, that it's not always feasible to get the testing done, especially when you have to deploy quickly, and to get testing done within the time period required.

In the event that plaintiff did, in fact, test positive, the military would be forced to scramble to find a replacement. The military shouldn't be forced to scramble in these types of situations.

Again, the Court raises the fact raised by the defendants that there are a number of host nations that require vaccination for members to enter their countries. And, again, that wasn't specifically addressed by the plaintiff in the opposition -- in the reply brief.

As another district court also explained, the speed of

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      transmission usually outpaces test results, making test result
 2
      availability not an effective alternative measure.
 3
               And then finally, masking and social distancing is
 4
      another means that was raised by the plaintiff. It's not,
      again, the Court finds, feasible under these circumstances and
 5
      given the plaintiff's specific responsibilities and duties in
 6
 7
      his role as the -- formally as the leader of -- I think it was
 8
      up to at least 40 men.
 9
               We lost Mr. Molloy again.
10
               Mr. Molloy, can you hear me?
                                             No.
11
               Ms. Enlow, can you hear me?
12
               MS. ENLOW: Yes. Your Honor.
13
               THE COURT: Okay. So it's just Mr. Molloy right now.
               You're in Washington, D.C., right?
14
15
               MS. ENLOW:
                           Yes, I am.
16
                          Okay. I think Mr. Molloy is in Texas.
               THE COURT:
17
               He's back.
18
               Can you hear me, Mr. Molloy?
19
               MR. MOLLOY: Yes, Your Honor, I can. Yes, Your Honor.
      I'm sorry.
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21
               THE COURT: Okay. All right. And so I -- my finding
22
      with respect to the preliminary injunction motion is that, in
23
      fact, the government has demonstrated that requiring the
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      vaccination -- requiring the plaintiff to be vaccinated, the
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COVID-19 vaccine, is, under these circumstances, these specific

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circumstances, the least restrictive means of furthering the compelling governmental interest.

And again, as I have mentioned previously, I recognize, and there's a lot of discussion in the cases that I read, that military members are not excluded from the protection of statutes or constitutional rights. That is discussed over and over again.

But these same cases also make it clear that the Court should be more deferential to the defendant's judgment on what is required to obtain maximum readiness of the military.

There's a case out of the District of Columbia,

Singh v. McHugh, which is cited by the defendants in that case.

The Court noted the need to respect military judgment while still applying RFRA's strict standard.

For those reasons, the Court does find that the government is likely to show that the vaccination is the least restrictive means of achieving a compelling interest and that the plaintiff is unlikely to succeed on the merits of the RFRA claim.

I also would find that the plaintiff has not demonstrated a likelihood of success on his free exercise claim.

The Supreme Court has held that the right of free exercise does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability on

the grounds that the law prescribes conduct that his religion prescribes.

A law that is neutral and of general applicability need not be justified by a compelling governmental interest even if the law has the incidental effect of burdening a particular religious practice. A law failing to satisfy these requirements must be justified by a compelling governmental interest and must be narrowly tailored to advance this interest.

There's a recent Ninth Circuit case and not a case involving military but involving a school district, *Doe v.*San Diego Unified School District, a 2021 Ninth Circuit case. In that case, the Ninth Circuit found that a student challenging her school district's vaccine mandate, which did not allow for a religious exception, was not likely to succeed on a free-exercise claim, as she had not raised a serious question about whether the mandate was neutral or generally applicable.

As to neutrality, the Ninth Circuit noted that the terms of the mandate did not make any reference to religion, nor had the student shown a likelihood that the mandate was implemented with the aim of suppressing religious belief rather than protecting the health and safety of students, staff and the community.

Turning to general applicability, the Court noted --

the Ninth Circuit noted that the only exempted students were those who qualified for a medical exemption, which furthered the government's interest in protecting student health and safety, and so it did not undermine the district's interest as a religious exception would and, accordingly, the mandate was subject to rational basis.

Similar to what is involved here, the terms of the Air Force mandate do not make any reference to religion, and plaintiff has not claimed and does not claim that the mandate was implemented with the aim of suppressing religious belief.

The fact that the Air Force has granted medical and administrative exemptions does not render the mandate not generally applicable. And as the Ninth Circuit recognized in the *Doe v. San Diego Unified School District* case, granting the medical exemption furthers their interest in ensuring military readiness and the health of their members as requiring a service member who is, for example, allergic to a component of the vaccine would harm their health.

Accordingly, these exemptions do not undermine the government's interests the way a religious exemption would and, thus, the government is likely to show that the mandate is generally applicable and does not violate the free exercise clause.

In the event that a court -- appellate court might believe, under the free exercise claim, that it's subject to

strict scrutiny for the same reasons that the Court has found that there's not a likelihood of success on the Religious Freedom Restoration Act, I also believe that the free exercise challenge would fail as well for the same reasons as the Court provided with respect to the Religious Freedom Restoration Act.

In terms of the likelihood of irreparable harm to the plaintiff and the other factors, given that the Court has found that there is not a likelihood of success on the merits of the two claims, the Court does not have to reach those issues, but I -- in terms of if it assists both the litigants and the appellate court, I think the irreparable harm issue is a close issue. I think it requires some further evidence.

There obviously is a number of cases, precedent, that indicates that there simply -- a court should find simply that there's a presumption of irreparable harm when a constitutional or statutory right has been infringed, but in a case where plaintiff has failed to demonstrate a sufficient likelihood of success on the merits, then a presumption wouldn't apply.

The plaintiff has argued that he is -- he's already suffered and he's likely to suffer irreversible harm to his career and reputation if he is removed from command.

I'm not sure the evidence is clear on that at this stage, as evidenced by the Court's questions on what could happen if he is ultimately successful in his lawsuit.

Military administrative and disciplinary actions,

including separation, are not, at least at this point in the Court's review of the evidence, not irreparable injuries.

It appears that the plaintiff could later be reinstated and provided backpay if he did prevail on his claim. So at this point I would find that the plaintiff, because he hasn't shown a likelihood of success, has also not met his burden on demonstrating a likelihood of irreparable harm.

And then the last factor is balance of equities in the injunction and public interest, third and fourth requirements of a preliminary injunction. Those two requirements merge when the government is involved. And in this case, again, court's are to give great deference to the professional judgment of military authorities concerning the relative importance of a particular military interest.

In *Winter*, the primary Supreme Court case that set forth the requirements for issuance of a preliminary injunction, the Supreme Court, in fact, reversed the granting of a preliminary injunction on the Navy on just the balance of equities in the injunction and the public interest factors alone.

The Court in *Winters* noted the importance of plaintiff's ecological, scientific and recreational interest in marine mammals but found those interests were plainly outweighed by the Navy's need to conduct realistic training exercises to ensure that it is able to neutralize the threat

posed by enemy submarines. Again, similarly here, the public's interest in military readiness and the efficient administration of the federal government does outweigh plaintiff's claims of job-related and pecuniary loss.

Serious questions have been raised. This is not, obviously, given what's gone on around the country in other cases, a case that district courts don't need further guidance on; but, as I mentioned, at this stage a preliminary injunction, especially enjoining the military, given all that's going on in the world at this time, it would be an extraordinary remedy in this Court's mind. And it can only be granted upon a clear showing that the plaintiff is entitled to the relief that he seeks here.

Courts should be and this court in particular is reluctant to enjoin the military when military readiness is at stake. I thought the discussion in the Texas case -- no. It was Georgia, I'm sorry -- by the judge in Georgia was particularly instructive even though I disagreed with where he came out on the issue, but there's a lot of discussion in this case and other cases I've seen in which the Court talks about how important it is for judges and district courts to seriously weigh what type of anticipated interference there is with the military function; would an injunction seriously impede the military in their performance of vital duties.

The cases strongly suggest that these type of cases

militate strongly against judicial review. We are entitled to review and the plaintiff is certainly entitled to his day in court, given the serious nature of his claim and the fact that it involves both statutory and constitutional issues.

But the judge in the Georgia case, again, which went in favor of the Air Force officer, it was an Air Force officer versus Lloyd Austin, says that "Courts must consider the extent to which the exercise of military expertise or discretion is involved, and courts should defer to the superior knowledge and experience of professionals in matters such as promotions or orders directly related to specific military function." And he writes over and over again, "Judges don't make good generals." I couldn't agree with that statement more.

These are difficult issues that you're asking a district court to make. And given the role of the military in protecting the American people and people around the world, I am reluctant to issue injunctive relief under these circumstances absent a clear -- a clearer or a clear showing that such injunctive relief should be granted.

That's really where I come out and where I disagree with the other cases that have been submitted, particularly by the plaintiff, where injunctive relief has been granted by the district court judge.

Hopefully I've made my decision clear, the basis for my decision. The motion for preliminary injunction is denied.

And I know that this will be pursued. Hopefully the transcript will be clear enough.

And again, I truly appreciate the lawyering in this case. I know it will continue as it moves up through the appellate courts. And given what's going on all around the country, it may end up in the Supreme Court. But thank you for contributing to the discussion and the legal issues, and we'll see where we end up. Thank you both.

Sorry, again, for the Zoom interruptions. We're going to go back to live hearings starting March 1st, so I appreciate your patience as well. Okay. Have a good afternoon.

MR. MOLLOY: Thank you, Your Honor.

MS. ENLOW: Thank you, Your Honor.

THE COURT: Thank you.

(Concluded at 3:29 p.m.)

JENNIFER COULTHARD - UNITED STATES DISTRICT COURT - (530)537-9312

1	CERTIFICATE
2	CERTIFICATE
3	I certify that the foregoing is a true and correct
4	
	transcript of the record of proceedings in the above-entitled
5	matter.
6 7	Jennifer L. COULTHARD, RMR, CRR DATE
8	Official Court Reporter
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Exhibit 10

DECLARATION OF DR. BRUCE M. MCCLENATHAN

I, Bruce M. McClenathan, hereby state and declare as follows:

1. I am a regional medical director of the Defense Health Agency-Immunization Healthcare

Division (DHA-IHD) stationed at Fort Bragg, North Carolina. During the development of the

Novavax NVX-CoV2373 vaccine, I was a member of the DHA and Preventive Medicine

Services' COVID-19 Vaccine Implementation Plan Team.

2. I am generally aware of the allegations set forth in the pleadings filed in this matter. I

make this declaration in my official capacity as DHA-IHD regional director and based upon my

personal knowledge and upon information that has been provided to me in the course of my

official duties.

Attached as Exhibit A is a true and correct copy of the memorandum, titled "Novavax 3.

COVID-19 Vaccine (NVX-CoV2373)-Information on Fetal Cell/Fetal Tissue," that I received

from Dr. Gale Smith, PhD, Senior Vice President for Discovery and Pre-clinical Research, and

Chief Scientist at Novavax, on or about 12 January 2022 in the course of my work on the

COVID-19 Vaccine Implementation Plan Team.

4. Novavax is available across the Department of Defense.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true

and correct. Executed this 5th day of August 2022.

MCCLENATHAN.BR Digitally signed by MCCLENATHAN.BRUCE.M.10755 UCE.M.1075595715 95715 Date: 2022.08.05 14:47:19 -04'00'

BRUCE M. MCCLENATHAN Regional Director

Immunization Healthcare Division

Exhibit A



Novavax COVID-19 Vaccine (NVX-CoV2373)-Information on Fetal Cell/Fetal Tissue

Novavax Medical Information is providing you this information in response to your request for medical information. You requested information regarding the use of fetal tissue or fetal cell lines in the development, confirmation, or production stages of the Novavax COVID-19 vaccine (NVX-CoV2373).

Novavax COVID-19 Vaccine Development

Novavax' NVX-CoV2373 vaccine is a recombinant protein vaccine, comprised of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike glycoproteins and a saponin based Matrix-M adjuvant.² The Novavax NVX-CoV2373 is produced in insect cells, not mammalian cells.

A genetic sequence for the coronavirus spike protein is cloned into the baculovirus and then infects the Sf9 insect cells to produce the spike protein antigen that is subsequently purified by filtration and chromatography. The saponin based Matrix-M adjuvant is based on the Quillaja saponaria Molina bark together with cholesterol and phospholipids. The adjuvant is designed to increase the immune response to the rSARS-CoV-2 protein.²

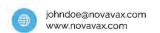
Animal or fetal-derived cell lines/tissue are not used in the manufacturing, testing, or production of the Novavax COVID-19 vaccine (NVX-CoV2373) administered in the clinical trials.

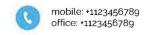
In early development, pre-clinical evaluation was conducted to compare the structural integrity of the SARS-CoV-2 spike protein produced in the Sf9 insect cells versus the spike protein produced in the mammalian immortalized human embryonic kidney HEK 293F cells. The comparison determined the Sf9 cell technology produced spike proteins that were comparable in structural integrity as the spike proteins produced in the HEK 293F cell.⁴ These pre-clinical experiments were conducted using purified SARS CoV-2 spike protein produced by a vendor separate from Novavax in a facility separate from where NVX-CoV2373 is manufactured and the assays did not employ fetal cells or tissues. Thus, no fetal cells or tissues are utilized at any time during the production or testing of NVX-CoV2373.

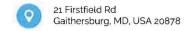
REFERENCE(S):

 Hu J, Han J, Li H, et al. Human Embryonic Kidney 293 Cells: A Vehicle for Biopharmaceutical Manufacturing, Structural Biology, and Electrophysiology. *Cells Tissues Organs*. 2018;205(1):1-8. doi: 10.1159/000485501. Epub 2018 Feb 1. PMID: 29393161.

Creating tomorrow's vaccines today.







- 2. Recombinant Nanoparticle Vaccine Technology. Novavax. https://www.novavax.com/our-unique-technology#recombinant-nanoparticle-vaccine-technology. Accessed December 18, 2020.
- 3. Data on File (1). Novavax, Inc., 2021.
- Bangaru S, Ozorowski G, Turner HL, et al. Structural Analysis of Full-Length SARS-CoV-2 Spike Protein From an Advanced Vaccine Candidate. *Science*. 2020 Nov 27;370(6520):1089-1094. doi: 10.1126/science.abe1502. Epub 2020 Oct 20. PMID: 33082295.

Dr. Gale Smith, PhD Senior Vice President

Discovery and Pre-clinical Research

Chief Scientist

